PLUS 9001

The ISO 9000:2000 Essentials

3rd Edition

A practical handbook for implementing the ISO 9000 Standards

Created by:
Pierre D. Landry
Health Canada
Ottawa, Canada

Contributors:
Pierre F. Caillibot
Chair ISO/TC 176
Montréal, Québec

Denis Pronovost
Accademia Qualitas
Montréal, Québec

Robert T. Marshall
Alcatel Canada Inc.
Toronto, Ontario

David Zimmerman
Canadian Standards Association
Toronto, Ontario

Malcom J. Phipps
QMI (Quality Management Institute)
Mississauga, Ontario

Acknowledgements
Figures and tables were kindly provided by Dr. Pierre F. Caillibot, Chair of ISO/TC 176, Pierre Landry of the Medical Devices Bureau of Health Canada, and Denis Pronovost of Accademia Qualitas, a private organization that teaches the application of ISO 9000 principles.

The editors would also like to thank the production staff of CSA: Managing Editor: Gary Burford, Administrative Assistant: Elizabeth Hope, Document Analyst: Indira Kumaralagan, Document Processor: Hematie Hassan, Editors: Maria Adragna, Samantha Coyle, Sandra Hawryn, Ann Martin, John McConnell, Graphics Coordinator: Cindy Kerkmann, Publishing System Coordinators: Ursula Das, Grace Da Silva, Seetha Rajagopalan, and SGML Project Manager: Alison MacIntosh

Published by
Canadian Standards Association
178 Rexdale Boulevard
Toronto, Ontario
Canada M9W 1R3

in association with

Quality Management Institute
90 Burnhamthorpe Road West, Suite 300
Mississauga, Ontario
Canada L5B 3C3

A DIVISION OF CSA GROUP

For information about this Handbook, and to order copies of publications referenced in it, please contact Canadian Standards Association or Quality Management Institute at the address given above or call 1-800-463-6727.

ISBN 1-55324-451-6

Contents

The ISO 9000 Essentials
A Practical Handbook for Implementing the Family of ISO 9000 Standards (3rd Edition)

Preface

The primary objective of this handbook is to provide both novice and experienced quality practitioners with a concise, user-friendly guide to understanding and implementing the requirements of ISO 9001:2000. The ISO 9000 family of Standards has undergone two revisions. Initially published in 1987, it was revised in1994 and in 2000.

The first part of the handbook is made up of three subsections: "Foreword", "Conceptual Overview", and "Implementation Path". The "Foreword" outlines the background of the ISO 9000:2000 family of standards and describes the changes that have occurred in these standards, compared with their 1994 versions. The "Conceptual Overview" describes some of the basic concepts, to help understand the fundamentals associated with quality management systems (QMS). Finally, the "Implementation Path" suggests an approach for QMS registration, and discusses of conformity assessment by third-party registration bodies (registrars) and accreditation bodies.

The second part of the handbook is also made up of subsections that are numbered according to corresponding clause numbers in ISO 9001:2000. This facilitates reading by allowing a direct link to all clauses of ISO 9001:2000 and ISO 9004:2000. Section 2 also contains

- the actual text of ISO 9001:2000
- guidance, made up of excerpts from ISO 9000-2:97, as well as other information available to the CAC/ISO/TC 176 (Canadian Advisory Committee to the ISO Technical Committee 176) and members of the editorial team
- numerous definitions extracted from ISO 9000:2000
- typical audit questions useful for organizations seeking to implement a QMS based on ISO 9001:2000
- self-diagnostic questions to be used by an organization while preparing its quality management system

Finally, in Section 3, several diagrams, tables, and appendices are provided to help understand the 9000:2000 family and its relationship to ISO 9001:1994.

The figures and tables were kindly provided by Dr. Pierre F. Caillibot, Chair of the ISO/TC 176, by Pierre Landry, of the Medical Devices Bureau of Health Canada, and convener of ISO/TC 176/WG2, and by Denis Pronovost of Accademia Qualitas, a private organization that teaches the application of ISO 9000 principles.

Layout of this Handbook

All clauses of ISO 9001:2000 are reproduced in a text box.

This section contains guidance extracted from the ISO PIP (Product Introduction Package prepared by ISO Technical Committee 176); or ISO 9000-2:97, or developed by members of the editorial team for this 3rd edition of PLUS 9001, as well as information made available to the Canadian Advisory Committee (CAC/ISO/TC 176).

SERVICE

This section contains information relevant to the service sector, eg, hotels, insurance companies, training providers, governments.

This section contains information relevant to computer software, in contrast to other types of intellectual software products such as music, movies, and stories.

Q/A

This icon, which appears only in Section 1, refers to the interpretation process related to the ISO 9001:2000 and its normative reference ISO 9000:2000. These sections also describe how to solicit interpretations. At time of publication of this handbook, no international interpretations, were available.

This section lists audit questions typical of those used by third-party QMS registrars.

This section provides definitions of terms from ISO 9000:2000, which are reproduced in Appendix B and from ISO/CD3 19011. Notes contained in these definitions are not always included in this section, but are all included in Appendix B.

This section lists diagnostic questions to be considered by the organization while preparing its QMS.

Abbreviations

CASCO: Conformity Assessment Committee of ISO
EMS: Environmental Management System
H&SS: Health and Safety System
IAF: International Accreditation Forum
ISO/TC 176: International Organization for Standardization Technical Committee 176 — Quality Management and Quality Assurance
PIP: Product Introduction Package
QMP: Quality Management Principles
QMS: Quality Management System

0. Introduction

0.1 General

The ISO 9000:2000 family of Standards was developed to assist organizations, of all types and sizes, to implement and operate an effective quality management system (QMS). It is made up of four core standards:

a) *ISO 9000:2000, entitled* Fundamentals and Vocabulary, *describes the fundamentals of a QMS and specifies the terminology for a QMS. It was developed on the basis of previous standards: ISO 8402:1994,* Vocabulary, *and ISO 9000-1:1994,* Selection and Use.

b) *ISO 9001:2000 specifies requirements for a QMS where an organization needs to demonstrate its ability to provide products that meet customer requirements and applicable regulatory requirements and aims to enhance customer satisfaction. The three quality assurance requirement standards ISO 9001:1994, ISO 9002:1994, and ISO 9003:1994 are replaced by a single quality management system requirement standard, ISO 9001:2000.*

c) *ISO 9004:2000,* QMS, Guidelines for performance improvement, *which replaces ISO 9004-1:1994, provides guidelines for both the effectiveness and efficiency of the QMS. The aim of this standard is the improvement of the performance of an organization and the satisfaction of customers and other interested parties. ISO 9004:2000, although considerably rewritten, was developed using the format and structure of ISO 9001:2000.*

d) *ISO 19011:2002 provides guidance on auditing quality and environmental management systems, and is presently being jointly developed by both ISO/TC 176 and ISO/TC 207. The ISO/TC 207 is responsible for the ISO 14000 family of environmental management standards. The first version is expected to be published in 2002 as ISO 19011, and will replace not only ISO 10011 Parts 1, 2, and 3, used for QMS auditing, but also the equivalent standards in the 14000 family, namely ISO 14010, ISO 14011, and ISO 14012, used for EMS auditing.*

Together the four ISO 9000 form a coherent set of QMS standards facilitating mutual understanding in national and international trade. Their relation to the 1994 edition of the 9000 family of standards is illustrated in Figure 1.

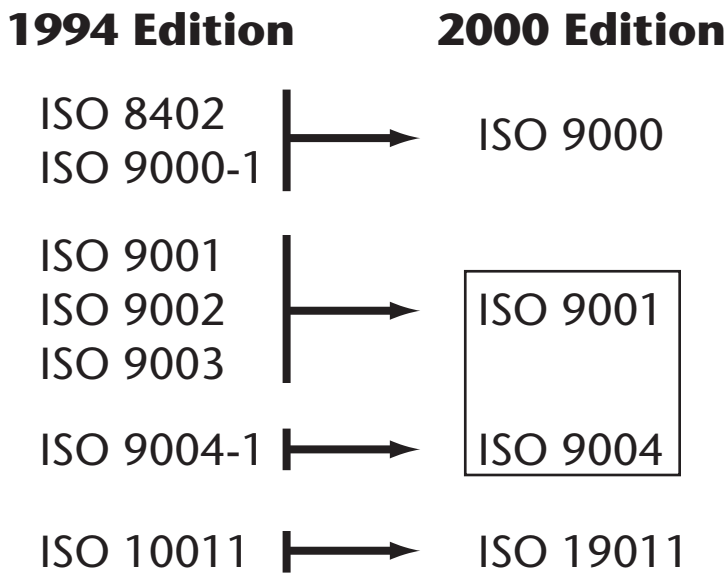


Figure 1
Correspondence Between the 1994 and 2000 Editions of the ISO 9000 Family

0.2 Rationale for QMS

A QMS assists organizations in enhancing customer satisfaction. Customers require products with characteristics that satisfy their needs and expectations. These needs and expectations, expressed in product specifications, are collectively referred to as "customer requirements". Customer requirements may be specified contractually by the customer or may be determined by the organization itself. In either case, the customer ultimately determines the acceptability of the product. Because customer needs and expectations tend to change, organizations are driven to continually improve their products and processes.

The QMS approach encourages organizations to analyze customer requirements, define the processes that contribute to the provision of a product that meets the specified requirements, and to keep these processes under control. A QMS can provide the framework for continual improvement to enhance the satisfaction of customer and other interested parties. It provides confidence to the organization and its customers that it can provide products that consistently fulfill requirements.

1. Foreword

1.1 ISO 9000 Family: Horizon 2000

The ISO 9000 family of standards was called a "phenomenon" a few years ago because, in just a few years, it was successful in replacing national standards in the field of quality assurance around the world. The market acceptance of these standards was also quite spectacular, although some predicted that this acceptance would soon reach a plateau. However, the latest survey conducted by ISO indicates that 343,643 certificates have been issued in 150 countries. Both numbers are astounding. Moreover, far from reaching a plateau, 1999 saw the largest yearly increase in certificates issued. Actually, more certificates were issued in that one year than in the first seven years following the standards' publication in 1987. Admittedly, certificates are only one indicator of the value that the ISO 9000 family provides to its users. But it certainly is a good indicator of the worldwide acceptance of these standards.

A quick look at different regions of the world shows that all of them are participating, from Central and South America — with close to 6000 — all the way to Europe — with close to 200,000. Figure 2 illustrates the world total and world growth numbers.

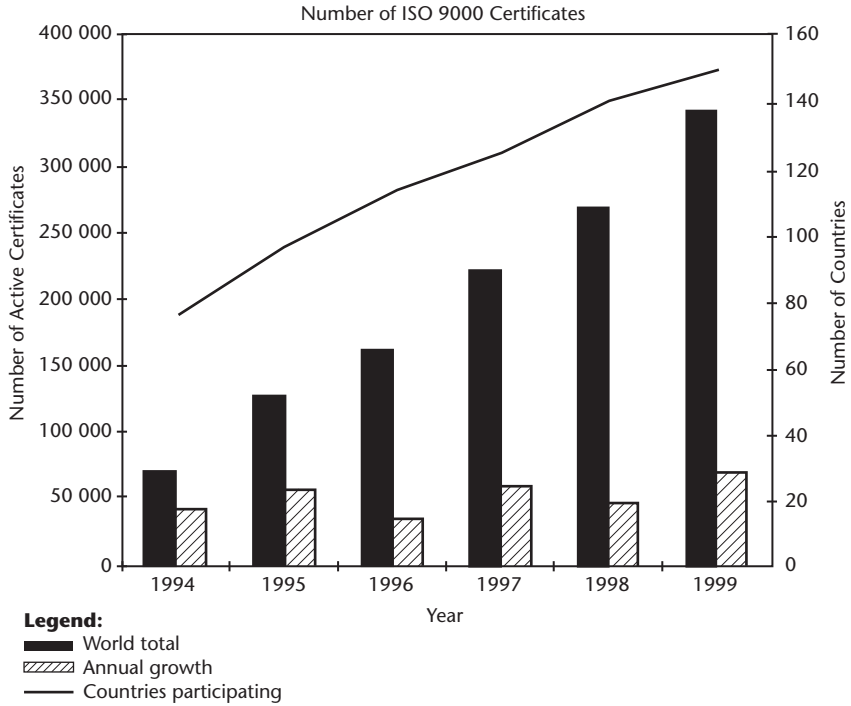


Figure 2
Number of ISO 9000 Certificates

Many rightly point out that the ISO 9000 standards must provide continuity, but, just as importantly, they have to provide relevance. This can only come from listening to the "voice of customers" in the many industry/economic sectors that are active participants in this international effort. One of the reported needs is to develop a process for the continual improvement of these standards. To address this need, ISO/TC 176 renewed its direction and reached consensus on

- a new vision and revised mission;
- the products and services needed to support and maintain the integrity of the 1994 editions; and
- the structure of the Year 2000 family of standards.

The new vision reads as follows:

> Through its worldwide acceptance and use, the ISO 9000 family of standards will provide an effective means for improving the performance of individual organizations and provide confidence to people and organizations that products, goods, and services will meet their expectations, thereby enhancing trade, global prosperity, and individual well-being.

1.2 Five Strategies

This vision was enacted through five key strategies:

a) The first strategy is to **provide a clear understanding of the role of quality in relation to the management of an organization and the application of related concepts and principles**. This has been a constant target while revising the ISO 9000 family of standards and in the development of informational guidance, brochures, and communiqués by ISO central secretariat. The informational documents were issued as press releases and in the journal *ISO 9000-ISO 14000 News,* as well as on the ISO and TC 176 Web sites. The new standard ISO 9000:2000, *Fundamentals and Vocabulary,* also contributes to this with information on a number of fundamentals of QMS.

b) The second strategy aims at **minimizing the proliferation of standards within the ISO 9000 family**. Currently, as indicated by Appendix A, this family comprises numerous standards, and it will be significantly reduced in size — but hopefully not in useful content — in the next year. An analysis was also made recently of the fate of the remaining standards or documents of the ISO 9000 family, some 20 in all. The final decision will be based on the results of voting by all ISO/TC 176 participating member countries.

   It is expected that most of the revision work will be completed by 2002. Following this, the whole family will have been updated to form a coherent set.

c) The third strategy is to **work toward minimizing the proliferation of standards, developed externally to ISO/TC 176, in the field of quality**

management by using a joint and cooperative approach with the relevant bodies. A major consideration has to do with the development of sectoral initiatives, of which there is a growing number. For example, significant initiatives are taking place in the automotive (eg, QS-9000), aerospace (eg, AS 9100), and telecommunications (eg, TL 9000) sectors. These initiatives have led to the development of two main types of documents that are based on ISO 9001: first, supplemental requirements to ISO 9001 in a supply-chain context (eg, QS-9000 for the automotive sector or ISO 13485 for medical devices), and second, guidance for the application of ISO 9001 in a particular sector (eg, ISO 14969 for medical devices). QS-9000 was developed outside the ISO, while ISO 13485 was developed by ISO/TC 210. A third type of initiative, of less importance, is based on ISO 9004.

The ISO has been working very hard over the past few years to ensure that it retains and develops the market relevance of its standards by serving the needs of users. To show the necessary flexibility and provide coherence, the ISO now offers a new set of coherent deliverables, representing different levels of consensus. At the lowest level we find the Industry Technical Agreements (ITA), which may result from a workshop. The highest level is the well-known, full-consensus document, the International Standard. There are three intermediate steps, the publicly available specification, the technical specification, and the technical report, which represent intermediate consensus levels. The relationship of all these levels is illustrated in Figure 3.

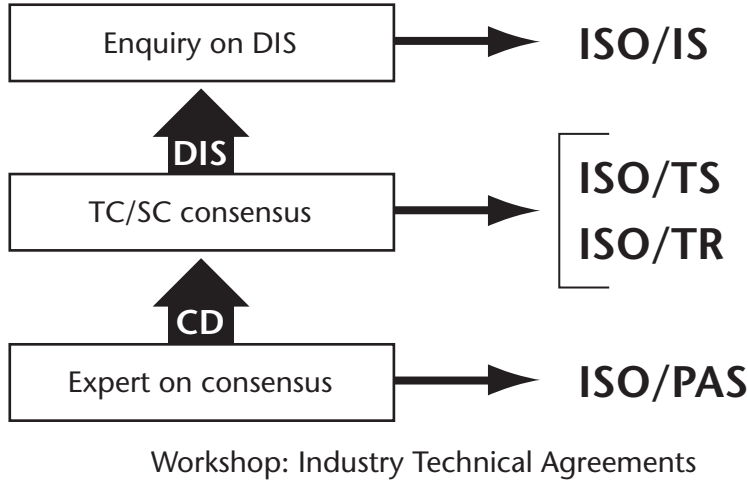


Figure 3
Consensus Levels

Provided by Accademia Qualitas

ISO/TC 176 is dedicated to developing generic standards for QMS. Nevertheless, it must be responsive to the needs of all users, including key sectors. For this reason, ISO/TC 176 piloted the first ISO technical specification, ISO 16949 for the automotive sector. Because of the growing number of sectoral initiatives, it was felt necessary to develop a sector policy to prevent or minimize the proliferation of sector documents and promote coherence among those that are actually developed. This sector policy, recently issued by the Central Secretariat of ISO/IEC, requires that ISO 9001:2000 be wholly referenced as mandatory requirements or be incorporated in its entirety into any new document based on it. If 9001:2000 is incorporated instead of being referenced, its full text must be readily distinguishable, either through boxes or typographical presentation, so that it is very clear which part of the document is the ISO 9001:2000 generic requirements and which part is supplementary sector application requirements or guidance.

d) The fourth strategy is to **ensure the integrity of the 9000 family of standards and to provide for the integrity of their implementation and of the evaluation of their implementation**. Many actions have been taken with the intent of preserving the integrity of ISO 9000 family. These include providing greater clarity in the standards themselves, greater clarity of the whole family, and translation tips to facilitate accurate translation. The question of translation of the standards is obviously of paramount importance in preserving their integrity. A Spanish translation task group was formed within ISO/TC 176 in 1999 to produce the first International Spanish edition of the core standards, with the view of replacing many differing national Spanish editions.

   Appropriate product support information was also developed. A formal interpretation process was established, which will contribute to minimizing the variations that may occur when different member bodies — different nations — interpret the standards on their own. More information on this is provided in Section 3.3.4 of this handbook.

   Guidance on the transition to the new standards was developed and published jointly by the ISO and the International Accreditation Forum (IAF), which comprises many of the accreditation bodies from around the world. Additional guidance was also developed on the application of ISO 9001, on the terminology used throughout the 9000:2000 family, and on the documentation requirements of ISO 9001:2000. These guidances are known as the PIP (Product Introduction Package).

e) The fifth strategy is to **maximize the usefulness of the ISO 9000 family of standards, facilitating its effective implementation in the context of other management systems, using a joint and cooperative approach**. For example, much effort with regard to this strategy is intended to improve

the compatibility between the relevant standards of the 9000 and 14000 families, and ISO 19011 (see Section 0.1 above) will have a favourable impact in this regard. In the future, there may be other generic management system standards to consider, such as financial management, occupational health and safety management, etc. More information is contained in the commentary on individual clauses of ISO 9001:2000 and in Appendix A of this handbook.

1.3 The Future

With the publication of the 2000 edition of the core standards, it has become very important to take a longer-term look at what the future will bring. The ISO/TC 176 mission, vision, and key strategies need to be updated. A strategic planning process is being conducted to update the ISO/TC 176 Strategic Plan. This document will pave the road for the future.

Clearly, ISO/TC 176 is reaching out, first by making sure that its core standards are pertinent to all sectors, all categories of users, all sizes of organizations, and also by reaching out to major users and purchasers, to ensure the market relevance of its documents. It is important to bridge the gaps created by the sometimes conflicting needs of different industrial sectors, gaps which may not be addressed by the generic documents. ISO/TC 176 is also reaching out to the conformity assessment community (accreditation and registration bodies), to promote horizontal thinking within ISO and a universal approach, to better serve the needs of users.

1.4 The Next Step: A Look at Certification Options

1.4.1 Overview

Inasmuch as both the 1994 and 2000 versions are expected to remain valid until December 2003, organizations have a number of options, depending of their exact needs and situation.

Let us look at some of these option by addressing four situations.

1.4.2 An Organization is Considering Implementing ISO 9001, ISO 9002, or ISO 9003 for the First Time

Organizations that are only now considering implementing, and possibly seeking registration to, ISO 9001, ISO 9002, or ISO 9003 should consider the following questions.

Should the 1994 or the 2000 edition of the standard be used?

Although the 1994 edition will continue to be recognized for three years, it is recommended to use the new 2000 edition at once. This will save the organization the need to upgrade at a later stage, and it will benefit from the increased flexibility and new features of the 2000 edition. Note, however, that

in the 2000 edition, ISO 9002 and ISO 9003 are no longer available options; still, greater flexibility is now offered by the exclusion provision of 9001:2000 (see the commentary on Clause 1.2 of ISO 9001:2000, later in this handbook).

What products and processes should be included in the QMS?
One of the first steps will be to make a decision about the desired scope of the organization's QMS or, in other words, about which products and product realization processes the QMS should apply to. In making this decision, the following should be considered:

- the nature of products and processes;
- the results of risk management activities;
- commercial considerations; and
- regulatory and contractual requirements.

It must be remembered that the standard itself does not require an organization to include all its products and processes within the scope of its QMS.

All organizations have a QMS, although some are minimal, and many are more or less informal. It is important that when implementing ISO 9001:2000, an organization takes full advantage of its current practices. The new standard gives organizations more flexibility in structuring the documentation of their QMS.

Should registration of the QMS be considered?
The decision to register may be a given, depending on commercial considerations and the regulatory and contractual requirements pertinent to an organization. For example, medical devices manufacturers in numerous countries must register their QMS to ISO 13485 or to ISO 13488. An organization may also decide to seek registration for the benefits and feedback received from an independent QMS registration body, ie, the third-party registrar that will audit the organization. It is important, however, to realize that the standard does not require third-party certification; the requirements alone may be used as an internal tool to give confidence to top management that the QMS is maintained in an effective state. It is also important to realize that the QMS is in place for the benefit of the organization and not to satisfy the demands of a registrar. A competent auditor will not alter the structure of a documented system (eg, a quality manual) or shift other aspects of a QMS away from what is considered as best adapted to the organization's products and processes.

1.4.3 An Organization Has Started Implementing ISO 9001:2000

Organizations that are presently in the process of implementing ISO 9001:1994, ISO 9002:1994, or ISO 9003:1994 should consider the following questions.

We have started to implement ISO 9001:1994: should we stop what we are doing and switch to ISO 9001:2000?
You should not stop what you are doing. Anything you do to lay the foundation of a QMS within your organization will be beneficial. However, you should consider reviewing the requirements of the new edition of ISO 9001:2000 and then reconsider the reasons that led you to implement ISO 9001:1994 in the first place. Would your organization be better served by the new edition? If so, you should conduct a gap analysis to identify the measures that would or would not be required to meet the 2000 edition instead of the 1994 edition. You should then incorporate any additional measures in your implementation plan.

We have started to implement ISO 9002:1994: what should we do?
Refer to the above answer. It also applies here. Additionally, if you perform design and development activities for products covered by your QMS certification, these design activities must be included in the scope of your registration to the ISO 9001:2000. This is explained in greater detail in this handbook, in Section 2.5, which deals with the exclusion requirement of ISO 9001:2000, and in Section 2, under Clause 1.2, "Application".

We have started to implement ISO 9003:1994 in our organization: what should we do?
Refer to the above answer. It applies here also. There are significant differences between ISO 9003:1994 and ISO 9001:1994, and even more significant ones between ISO 9003:1994 and ISO 9001:2000, most notably in connection with product realization activities. It is therefore probable that analysis will reveal significant gaps that will need to be addressed to secure conformity. Adapt your implementation plan to the needs of your organization, your priorities, and the availability of resources that will be required.

1.4.4 Your Organization is Considering Upgrading its QMS

Organizations that have already implemented ISO 9001:1994, ISO 9002:1994, or ISO 9003:1994, and are considering upgrading their QMS to meet ISO 9001:2000 or to go beyond ISO 9001:2000, should consider the following questions.

Our QMS meets ISO 9001:1994 (or ISO 9002:1994, or ISO 9003:1994). We would like to upgrade it to meet ISO 9001:2000. What should we do?
The requirements of the new edition of ISO 9001:2000 need to be reviewed, to ensure they are fully understood. A gap analysis also needs to be conducted to identify measures in your QMS that will be required to meet the 2000 edition instead of the 1994 edition, and to establish a realistic implementation plan. Refer to the section dealing with an implementation path in this handbook for more information; see too Appendix B, which shows the correspondence between the 1994 and 2000 versions.

Our QMS meets ISO 9001:2000. We would like to upgrade it. What are our options?

There are a number of options. Here are four:

a) The successful use of the eight quality management principles by the organization should result in benefit to all its interested parties, and should be considered to identify areas of improvement of the QMS. ISO has published a brochure listing them, and they are also included both in ISO 9000:2000 and ISO 9004:2000; they are also summarized in Section 2.1 of this handbook.

b) ISO 9004:2000 was developed to be consistent in structure, terminology, and contents with ISO 9001:2000. It should be noted that ISO 9004:2000 is not intended for certification, regulatory, or contractual use, nor as a guide for the implementation of ISO 9001:2000. The relationship between the two standards is illustrated in Section 2.3 and in Table 3 of this handbook. The scope of ISO 9004:2000 is much broader than that of ISO 9001:2000. It provides guidelines to organizations for performance improvement. It gives guidance on the systematic application of quality management to improve an organization's processes in order to achieve effective and efficient performance. It assists an organization in establishing, documenting, implementing, maintaining, and improving its QMS, and may be used to evaluate and improve its "maturity". The concept of self-assessment described in ISO 9004:2000 may prove quite useful for an organization in evaluating and improving the maturity of its QMS.

c) In addition to ISO 9004, the ISO 9000 family comprises a number of other useful guidance documents. These documents should be consulted to identify possible improvement areas of the QMS:

- ISO 10006 — *Guidelines to quality in project management*
- ISO 10007 — *Quality management — Guidelines for configuration management*
- ISO 10012 — *Quality assurance requirements for measuring equipment*
- ISO 10013 — *Guidelines for developing quality manuals*
- ISO/TR 10014 — *Guidelines for managing economics of quality*
- ISO 10015 — *Guidelines for training*
- ISO/TR 10017 — *Guidance on statistical techniques for ISO 9001:1994*
- ISO 19011 — *Guidelines for auditing management systems*

d) ISO 9004 can be a bridge between ISO 9001:2000 and a number of recognized organizational excellence models. These contain criteria that enable a comparative evaluation of organizational performance. This is applicable to all activities and all interested parties of an organization. Using such models can help an organization identify further areas for improvement for its QMS.

1.4.5 The Organization is Considering Upgrading its Registration to ISO 9001:2000

Organizations that are already registered to ISO 9001:1994, ISO 9002:1994, or ISO 9003:1994, and are considering upgrading their registration to ISO 9001:2000, should consider the following questions.

Our QMS is registered to ISO 9001:1994 (or ISO 9002:1994 or ISO 9003:1994). Can we remain registered to this standard?

Organizations are encouraged to make the transition to ISO 9001:2000 as soon as possible; however, according to IAF/ISO Communiqué on transition policy, during this three-year transition period, organizations may choose to continue or even to seek new registration to the 1994 versions of ISO 9001, ISO 9002, and ISO 9003. However, any certificates issued or renewed will only remain valid for a maximum of three years after the publication of ISO 9001:2000.

Our QMS is registered to ISO 9001:1994 (or ISO 9002:1994 or ISO 9003:1994). We want to upgrade our registration to ISO 9001:2000. What should we do?

The first step is to upgrade the QMS to meet the requirements of ISO 9001:2000, as discussed above. In addition, contact the registrar to indicate your intention so that appropriate plans can be developed. For instance, registrars may be able to coordinate the usual surveillance audit with the audit leading to the new registration, thereby saving time and minimizing costs.

It should be noted that accredited registrars have been informed jointly by ISO and the International Accreditation Forum (IAF) that

a) Certificates issued to the 1994 editions of ISO 9001:1994, ISO 9002:1994, or ISO 9003:1994 shall have a maximum validity of three years from the date of publication of ISO 9001:2000 (December 2000).

b) Registrars will need to take particular care in defining the scope of certificates issued to ISO 9001:2000 and the applicable exclusions to the requirements of the standards.

1.5 ISO 9000:2000 Family Compared to the 1994 Family

1.5.1 Overview

Much has been said and written about the changes made to the ISO 9001 Standard for the new edition. But more than changes to ISO 9001 are involved: the entire ISO 9000 family of Standards is undergoing changes, with a potentially huge reduction in the number of standards, greater consistency between the standards, and better terminology, to mention only a few. Other changes are less obvious; many resulted from an international user survey that confirmed, among other things, that

- the 1994 standards had a high "manufacturing flavour";
- the 20 elements were not well-suited to most organizations; and
- there were too many standards and documents within the 9000 family.

To resolve these shortcomings, the ISO 9000:2000 family now has a core of four standards, as illustrated in Figure 1. ISO 9001 and ISO 9004 have been structured and written as a "consistent pair"; they have the same structure, and the actual text of the requirements of ISO 9001 is included in ISO 9004, as boxed text. Furthermore, ISO 19011 is designed to be a single auditing standard, applicable to both quality and environment management systems. When published, ISO 19011 will replace the three-part ISO 10011 series, as well as the corresponding standards in the 14000 family, ISO 14010, ISO 14011, and ISO 14012.

All other standards and guidelines have been, are being, or will be questioned as to their relevance and value for end users. Some will remain International Standards, such as ISO 10012, on measuring equipment. Others will be transferred to another working group, such as ISO 9000-3, on computer software. Still others will be revised and published as Technical Reports, Publicly Available Specifications, or Industry Technical Agreements. As described in the Foreword, the remaining documents will be cancelled, mainly because their contents have been included in the core standards or have become obsolete.

1.5.2 Bases of the Standards

A large effort has been made to lay the proper foundations for the new ISO 9000:2000 family. Part of that effort was to improve the terminology, both in terms of the structure of the definitions and in terms of their applicability in the guidelines for performance improvements (ISO 9004:2000) and the requirements (ISO 9001:2000). The standard now known as ISO 9000:2000 contains 82 definitions grouped according to ten themes: quality, management, organization, process and product, characteristics, conformity, documentation, examination, audit, and quality assurance for measurement processes.

Another part of the effort was to use the quality management principles (QMP), especially Principle #4, "Process approach", and Principle #5, "System approach", as the underlying concepts for both the guidelines (9004) and the requirements (9001). These QMPs are discussed in Section 2.1 of this handbook. The ISO 9000:2000 family promotes the use of the process approach when developing and structuring the various QMS activities of an organization, and the system approach when defining the sequence and interactions between the processes. The use of these QMPs has led to a model of a process-based QMS, as shown in Figure 4.

1.5.3 The Process Approach

ISO 9001:2000 promotes the adoption of a process approach when developing, implementing, and improving the effectiveness of a QMS, so as to enhance customer satisfaction by meeting customer requirements. For an organization to function effectively, it has to identify and manage numerous linked activities. An activity that uses resources, and that is managed in order to enable the transformation of inputs into outputs, can be considered a process. Often the output from one process directly forms the input to the next. Figure 10, "Process Control", illustrates an approach to controlling the expected results from any process that is applicable to all processes of the QMS (ie, Clauses 4, 5, 6, 7, and 8, not just those of Clause 7).

The application of a system of processes within an organization, together with the identification and interaction of these processes and their management, can be referred to as the "process approach". An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a QMS, such an approach emphasizes the importance of

- understanding and fulfilling requirements;
- the need to consider processes in terms of added value;
- obtaining results of process performance and effectiveness; and
- continual improvement of processes based on objective measurement.

The model of a process-based QMS shown in Figure 4 illustrates the process linkages described in Clauses 4 to 8 of ISO 9001:2000. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 4 covers all the requirements of this International Standard, but does not show processes at a detailed level.

In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows:

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives, and requirements for the product and report the results.

Act: take actions to continually improve process performance.

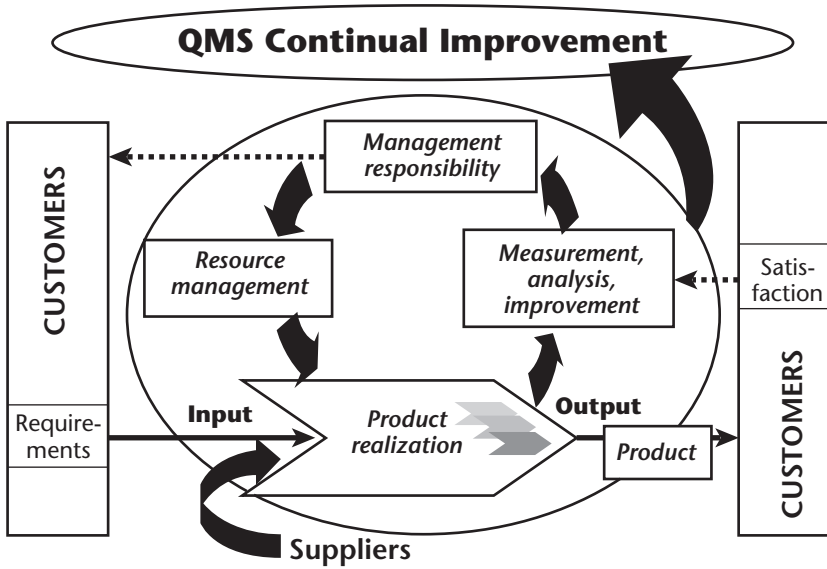


Figure 4
QMS Continual Improvement Diagram

This model has been used to structure the ISO 9001 and ISO 9004 standards, as can be seen from their identical table of contents, reproduced below:

1. Scope
2. Normative reference
3. Terms and definitions
4. Quality management system
5. Management responsibility
6. Resource management
7. Product realization
8. Measurement, analysis and improvement

Since this model is linked to all eight quality management principles (QMPs), the influence of these QMPs is visible in the contents of ISO 9001:2000, and even more so in ISO 9004:2000.

1.5.4 Changes in ISO 9001

All four core standards in the year 2000 family have gone through important changes. As this handbook is focused on ISO 9001, the important changes in ISO 9001 must be summarized briefly.

Although the changes are important, quality management and quality assurance have not been reinvented. Much of ISO 9001:1994 is to be found in ISO 9001:2000. Many of the clauses or subclauses of ISO 9001:1994 are reproduced nearly verbatim in the new standard, with a different clause number. Some clauses of ISO 9001:1994 with a very strong "manufacturing flavour", and those that were more appropriate to large organizations, were redesigned and rewritten to be more palatable to all organizations, including those involved with service and software, as well as small and medium-sized enterprises. (Appendix C shows the correspondence between 9001:1994 and 9001:2000.)

Table 1
Comparison of Past and Present Editions of ISO 9001

ISO 9001: 1994 Edition	ISO 9001: Year 2000 Edition
Language oriented towards "hardware" product	Clearly addresses all categories of products
Focused on manufacturing process and product cycle	More generic approach addressing all functions of the organization that directly affect product quality
Three-model format with limited scopes	Single model, offering greater flexibility
Structure of 20 QMS elements	Logical structure of linked processes
Has led to mainly subjective measurements of compliance	Emphasizes that it is important to evaluate and improve the effectiveness of the QMS based on objective measures
Offers no linkage to ISO 9004 to identify the QA/QM relationship	Structure is fully aligned to ISO 9004

One significant change that is often overlooked concerns the Scope statement. The Scope in ISO 9001:1994 was

> This International Standard specifies quality system requirements for use where a supplier's capability to design and supply conforming product needs to be demonstrated. The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from design through to servicing.

The Scope in ISO 9001:2000 reads as follows (words are not underlined in the standard):

> This International Standard specifies requirements for a quality management system where an organization
>
> a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

The underlined words show that an emphasis is now placed on consistently providing a conforming product, on enhancing/augmenting customer satisfaction, and on continual improvement. Other than the Scope, the more obvious changes and additions can be grouped in four areas: involvement of top management, customer focus, management by facts, and continual improvement. Each of these four areas in ISO 9001:2000 is related to QMPs.

1. Involvement of top management

The QMP on "Leadership" is embedded in Clause 5 of ISO 9001:2000, which deals with management responsibility; there it is emphasized that some responsibilities must be assumed by "top management", and not just "management with executive responsibility", as in the 1994 edition. Furthermore, commitment cannot be limited to signing the quality policy. Subclause 5.1 specifies that the top management commitment to the QMS and its continual improvement must be demonstrated by

- establishing the quality policy;
- ensuring that quality objectives are established;
- communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements;
- conducting management reviews; and
- ensuring the availability of resources.

This top management commitment emphasizes that the QMS is an integral part of an organization's management systems, and that it requires a level of attention equivalent to other management systems.

2. Customer focus

The QMP on "Customer focus" shows up in many subclauses of the new standard. Clause 5.2, Customer focus, specifies that top management must participate in the processes which "ensure that customer requirements are determined and met with the aim of enhancing customer satisfaction". The words "enhancing customer satisfaction" mean more than just maintaining satisfaction, and much more than just delivering conforming products. In order to know whether satisfaction has been augmented, an organization needs to measure it, as required by Clause 8.2.1.

The organization must have methods to obtain and use customers' perceptions on whether their requirements have been met. Customer satisfaction will likely be achieved if Clauses 7.2.1, Determination of requirements related to the

product, and 7.2.3, Customer communication, are implemented. The first specifies that the organization define all requirements related to its product, which includes stated and implied customer needs, as well as regulatory and internal requirements. The second requires that the organization define effective communication channels with customers while products are being produced, in order to easily exchange product and process information, as well as customer feedback.

3. Management by facts

The QMP on "Factual approach to decision making" is built into ISO 9001:2000 through two main clauses, 5.4.1, Quality objectives, and 8.4, Analysis of data. The former specifies that quality objectives be set for all relevant levels and functions within the organization, including objectives related to the product, and, most important, that these objectives be measurable. The latter requires factual data to be collected from various sources, such as the measurement and monitoring of products and processes, trends in processes, customer satisfaction, and supplier performance, and be analyzed to provide useful information for decision-making. Other clauses point to factual data and information, such as 6.2.2, Competence, awareness and training, which requires an organization to evaluate the effectiveness of the training actions taken.

The requirement to base decisions on factual data is not limited to top management performing management reviews. Measurable objectives are to be determined at every level of the organization. Data is to be collected on products and processes, and then the analysis of data must provide useful information for factual decision-making at all levels and for all functions of the organization.

4. Continual improvement

The QMP on "Continual improvement" has pushed its roots into many clauses of the standard, particularly 5.3, Quality Policy, 5.6, Management review, 8.1, General, 8.4, Analysis of data, and 8.5.1, Continual improvement. The latter requires that an organization continually improves the effectiveness of its QMS. Without top management support, a continual improvement program can not be implemented. Clause 5.3 addresses this by requiring that top management include a commitment to continual improvement in the quality policy. A process needs to be planned and implemented (8.1), and data must be collected and analyzed in order to identify areas where improvements can be made (8.4); this information is to be included in the management review process for proper decisions (5.6).

Continual improvement is not limited to the QMS. Although this minimum requirement is specified in Clause 8.5.1, it is expected that process and product improvements will result from the management review process. Clause 5.6.3,

Review output, is clear:

> The output from the management review shall include any decisions and actions related to
> (a) improvement of the effectiveness of the quality management system and its processes,
> (b) improvement of product related to customer requirements, and
> (c) resource needs.

2. Conceptual Overview

2.1 Quality Management Principles

The following eight quality management principles (QMPs) are derived from the collective experience and knowledge of internationally respected experts, and aimed at helping users achieve sustained organizational success. A brochure containing further information describing how these principles form the basis for the QMS standards within the ISO 9000 family is published by ISO. This brochure describes each of these principles, highlights the benefits derived from their use, and provides examples of actions that managers typically take to improve their organizations' performance.

In order to lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Managing an organization encompasses quality management, among other management disciplines.

Table 2
Quality Management Principles

1. Customer focus
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision-making
8. Mutually beneficial supplier relationships

1. **Customer focus:** organizations depend on their customers and therefore should understand current and future customer needs, meet customer requirements, and strive to exceed customer expectations.

2. **Leadership:** leaders establish unity of purpose and the direction of the organization. They should create and maintain an internal environment in which people can become fully involved in achieving the organization's objectives.

3. **Involvement of people:** people at all levels are the essence of an organization, and their full involvement enables their abilities to be used for the organization's benefit.

4. **Process approach:** a desired result is achieved more efficiently when related resources and activities are managed as a process.

5. **System approach to management:** identifying, understanding, and managing a system of interrelated processes for a given objective improves the organization's effectiveness and efficiency.

6. **Continual improvement:** continual improvement should be a permanent objective of the organization.

7. **Factual approach to decision-making:** effective decisions are based on the analysis of data and information.

8. **Mutually beneficial supplier relationships:** an organization and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.

2.2 Requirements for Products and Requirements for Quality Management Systems

The ISO 9000 family distinguishes between requirements for QMSs and requirements for products. Requirements for QMSs are specified in ISO 9001. Requirements for QMSs are generic and applicable to organizations in any industry or economic sector, regardless of the offered product category. ISO 9001 itself does not establish requirements for products.

Delivering a product that meets user requirements involves a dual approach. On the one hand, a product must often conform to specified technical specifications that address certain attributes related to product performance and characteristics. On the other hand, the organization must ensure that these attributes are consistently built into or incorporated in the product. This dual approach is depicted in Figure 5. The ISO 9000 family of standards, and hence this handbook, relate specifically to the QMS practices within an organization. Technical specifications and standards related to product or process can be contained in, for example, technical specifications, product standards, process standards, contractual agreements, and regulatory requirements.

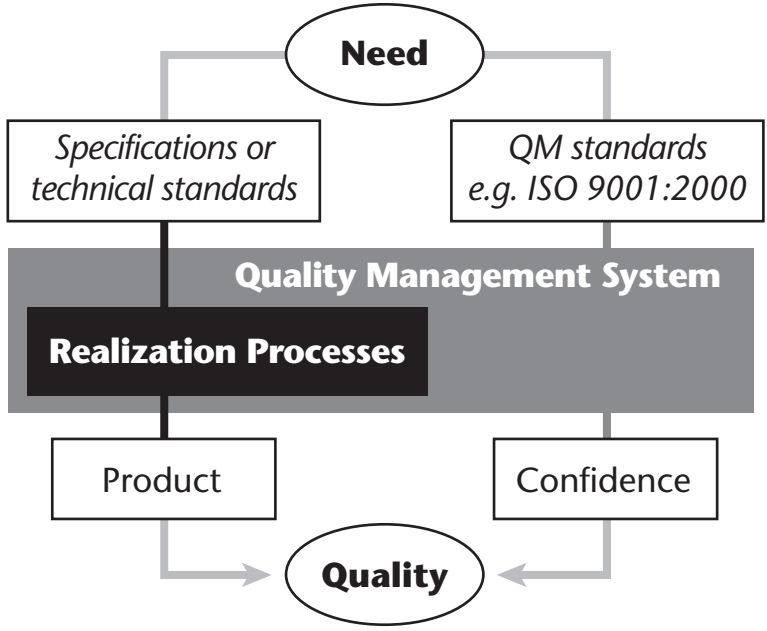


Figure 5
Quality: Product and Confidence

2.3 Relationship Between ISO 9001 and ISO 9004

Table 3 illustrates a standard that states requirements (ISO 9001:2000) in relation to a standard that gives guidelines for performance improvements (ISO 9004:2000).

Table 3
ISO 9001:2000 and ISO 9004:2000

Requirement Standard ISO 9001:2000	Guideline for Performance Improvement ISO 9004:2000
Enhance customer satisfaction through meeting customer requirements (including having product meet customer requirements)	Achieve competitive advantage through exceeding customer requirements (including having product meet enhanced expectations)
Effectiveness	Efficiency
Minimum set of requirements	The best practice
Compliance to the requirements which are auditable	Guidance, not requirements
Requirements either have or have not been met	Degrees of excellence
Ability to achieve customer requirements and improve processes by reducing risks and preventing failure	Ability to achieve superior performance and delighted customers

Figure 6 also illustrates the relationship between ISO 9001:2000, ISO 9004:2000, and other quality management system standards (here, ISO 13485 for medical devices is used to illustrate such a link). The figure shows that ISO 9004:2000 is an excellent tool to efficiently satisfy the needs of the customers and other interested parties, while ISO 9001:2000 or ISO 13485 provide confidence to stakeholders or regulators. It also shows how a QMS can be used for internal or external purposes.

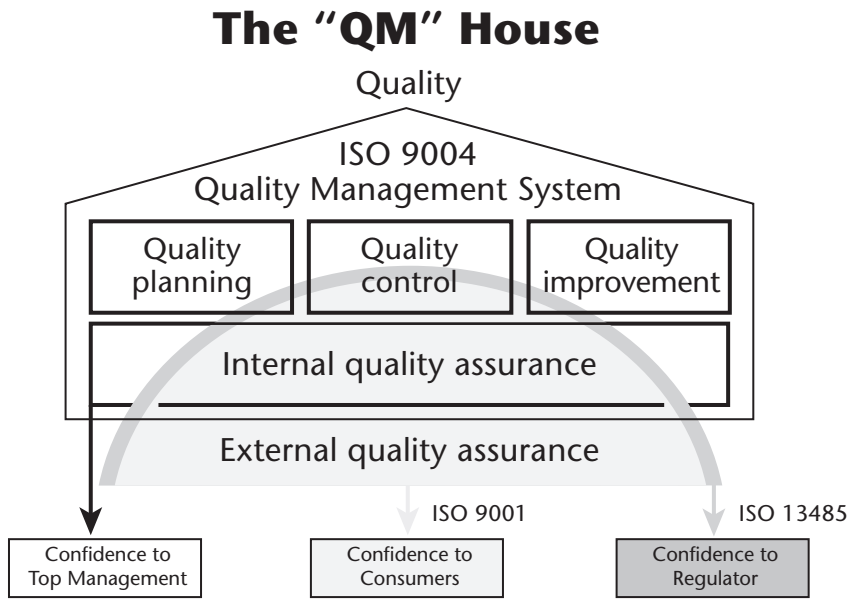


Figure 6
The "QM" House

2.4 Exclusion of Requirements

2.4.1 Overview

Under certain circumstances, an organization may justify the exclusion of some specific ISO 9001:2000 requirements (limited to Clause 7) from its QMS. ISO 9001:2000 makes allowance for such organizations in Clause 1.2, Application.

For an example of the degree of flexibility of the exclusion, see the "Service" comments in section 2.4.9 of this handbook.

The ISO/TC 176 prepared a *Product Introduction Package* (*PIP*) that contains several modules explaining different aspects related to ISO 9000:2000 and ISO 9001:2000. The information in this section is excerpted from the module "Guidance on ISO 9001:2000 Clause 1.2, Application".

2.4.2 The Scope of a QMS

ISO 9001:2000 Clause 1, Scope, defines the scope of the standard itself. This should not be confused with the scope of the QMS, which is a term commonly used within the context of QMS certification/registration to describe the products and product realization processes to which the QMS is applied.

The scope of the QMS should be based on the nature of the organization's products and their realization processes, the result of risk assessment, commercial considerations, and contractual, statutory, and regulatory requirements. An organization is not obliged to include all the products that it provides within the scope of its QMS, or to address the realization processes for products that are not included within the QMS.

If an organization chooses to implement a QMS with a limited scope, however, this should be clearly defined in the organization's quality manual and any other publicly available documents, to avoid confusing or misleading customers and end users (such documents include, for example, certification/registration documents and marketing material).

2.4.3 Application of ISO 9001:2000

It is intended that organizations seeking to implement ISO 9001:2000 should comply with all the requirements of the standard that are applicable to the products and product realization processes within the scope of the QMS.

However, even when an organization includes all its products and processes in the scope of its QMS, it may be found that some of the requirements of Clause 7 of ISO 9001:2000, Product realization, cannot be applied. This could be due to the nature of the organization, or that of its products or realization processes. In such circumstances, the organization would need to limit the application of the requirements of ISO 9001:2000, in accordance with Clause 1.2.

It should be noted that Clause 1.2 of ISO 9001:2000 is not intended to apply only to entire clauses; there may be circumstances where specific requirements within one of the subclauses of Clause 7 are applicable, while others can be excluded. An example would be within Clause 7.5.3, where traceability requirements may be considered for exclusion, but not the requirements regarding identification.

2.4.4 Justification of Exclusions

Where an organization finds that it is necessary to limit the application of the requirements of ISO 9001:2000, this must be defined and justified in the organization's quality manual. As with the case of a reduced scope of the QMS, the application of ISO 9001:2000 requirements must also be clear in any other publicly available documents, such as certification/registration documents or marketing materials, to avoid confusing or misleading customers and end users.

Clause 4.2.2(a) of ISO 9001:2000, Quality manual, requires that

> The organization shall establish and maintain a **quality manual** that includes the following:
> a) the scope of the QMS, including details of and justification for any exclusions (see 1.2)....

2.4.5 Most Likely Exclusions

Within Clause 7, Product realization, the following are the most likely (though not the only) requirements that could be considered as not being applicable in certain circumstances:

- 7.3, Design and development, where the organization has no responsibility for the design and development of the products it provides.
- 7.5.3, Identification and traceability; this clause would only be partially applicable where there is no specific traceability requirement for the organization's products.
- 7.5.4, Customer property, where the organization uses no customer property in its product or product realization processes. Note that if the customer provides a proprietary design for the product, this may constitute intellectual property and must be covered by the organization's QMS.
- 7.6, Control of monitoring and measuring devices, where the organization needs no monitoring or measuring devices to provide evidence of conformity of its product. This may be the case for some service organizations, among others.

2.4.6 Requirements That May Not Be Excluded, and Claims of Conformity

If an organization excludes from its QMS ISO 9000:2000 requirements that do not meet the criteria established in Clause 1.2, Application, then conformity to ISO 9001:2000 may not be claimed or implied. This includes the following situations:

- where an organization fails to comply with the requirement in Clause 4.2.2(a), Quality manual, to provide justification for the exclusion of specific Clause 7, Product realization, requirements;
- where an organization decides not to apply a requirement in Clause 7 based only on the justification that this was not a requirement of either ISO 9001:1994, ISO 9002:1994, or ISO 9003:1994, and had not been previously included in the organization's QMS; and
- where requirements in Clause 7 have been excluded because they are not required by regulatory bodies, but this affects the organization's ability to meet customer requirements.

2.4.7 Subcontracted or "Outsourced" Processes

Where the overall responsibility for product realization belongs to an organization, the fact that a specific product realization process (such as product design and development or manufacturing) is outsourced or subcontracted to an external supplier is not an adequate justification for the exclusion of the process from the QMS. Instead, the organization must be able to demonstrate that it

exercises sufficient control to ensure that such processes are performed according to the relevant requirements of ISO 9001:2000. The nature of this control will depend on the nature of the outsourced or subcontracted process and the risk involved. It may include, for example

- the specification and/or validation of processes as part of the contractual agreement with the supplier;
- requirements for the supplier's QMS; and
- on-site inspections, verifications, or audits.

Clause 7.4 of ISO 9001:2000, Purchasing, must be used to monitor the output of these outsourced or subcontracted processes.

2.4.8 Certification/Registration

A clear description of the scope of an organization's QMS and the application of the requirements of ISO 9001:2000 within that scope is of increased importance for certification/registration purposes, since there will no longer be the option to issue certificates to ISO 9002 or 9003. This has been recognized in the September 1999 communiqué of the IAF-ISO/TC176-ISO/CASCO(1) joint group responsible for defining transition policy. This communiqué establishes requirements for certification bodies during the transition period from the use of the 1994 standards to the use of ISO 9001:2000, and specifically requires that certification/registration bodies will need to take particular care in defining the scope of certificates issued to ISO 9001:2000, and the exclusions to the requirements of that standard.

In addition, certification/registration bodies are required to comply with the requirements of Clause 3.5.3 of ISO/IEC Guide 62, *General requirements for bodies operating assessment and certification/registration of quality systems,* to ensure that certification/registration documents are not misleading and reflect correctly the products and product realization processes that are within the scope of the QMS.

2.4.9 Examples

The following are examples taken from a set of examples contained in the PIP entitled *Guidance on ISO 9001:2000 clause 1.2 Application*, where the requirements in Clause 7 of ISO 9001:2000 may or may not be applicable to an organization. It is stressed that these are only hypothetical examples, and that each example should be analyzed carefully. Situations will occur in which organizations may justifiably exclude other ISO 9001:2000 requirements from Clause 7 from their QMS, either wholly or partially.

SERVICE

ABC Bank provides a variety of services to its customers, but chooses to implement a QMS only for its on-line Internet banking services. This is acceptable, provided that any

associated documentation (quality manual, any eventual QMS certification, and promotional material) makes it clear which services are covered by the QMS. The bank applies all the requirements of ISO 9001:2000 for the realization of its Internet banking service, without any exclusions. Initially the bank had excluded Clause 7.5.3 from its QMS, but then realized that its customers do indeed provide important personal information in confidence, when signing up for the service, and that this constitutes "customer property".

HIJ & Partners is a firm of international lawyers that has implemented a QMS based on ISO 9001:2000. The QMS includes the design and development of new services such as international tax planning, as well as changes to the design of existing services to take advantage of worldwide electronic databases of applicable legislation. HIJ also designs and develops customized services to meet specific customer requirements. Purchasing control includes the selection of computer hardware and software, as well as the subcontracting of specialist lawyers as needed. The only exclusion to ISO 9001:2000 (justified in the quality manual) relates to Clause 7.6, Control of measuring and monitoring devices, since this specific law firm does not use measuring or monitoring devices in carrying out its business realization processes.

KML Medical designs and produces medical devices according to strict product codes and regulations. KML Medical has a QMS that was originally certified/registered according to ISO 9002:1994, because the regulations did not require the QMS to include design for the risk class of devices KML produces. The regulatory authority has not yet revised its rules to take into account the new ISO 9001:2000, but has confirmed that it will continue not to require the QMS to include the design activity for this risk class of devices. KML Medical decides not to exclude Clause 7.3, Design and development, from its QMS, however, because it does in fact carry out this activity, and the activity does affect its ability to meet customer requirements. Also, KML wants to be able to claim conformity with ISO 9001:2000, and the exclusion of the design and development activity would not allow it to do so.

TCH Enterprise has decided to launch a new product. Although TCH owns the conceptual design, the detailed design calculations are outsourced to HT&T Inc., who provides detailed product specifications as HT&T's output to TCH Enterprise. These specifications are, in turn, passed on to CBB Construction for the manufacture of the product. In this case, the requirements of Clause 7 of ISO 9001:2000 are applicable as follows:

Clause	TCH	HT&T	CBB	Comment
7.1	Applicable	Applicable	Applicable	
7.2	Applicable	Applicable	Applicable	
7.3	Applicable	Applicable	Not applicable	
7.4	Applicable	Applicable	Applicable	
7.5	Applicable	Applicable	Applicable	
7.5	Applicable	Applicable	Applicable	
7.6	Applicable	Applicable	Applicable	If measuring and monitoring devices are used

SERVICE

CDH Construction Ltd. designs, develops, and constructs buildings, but does not have an in-house design capability. This company employs a project manager who is responsible for the management of design activities, which are subcontracted to TPL Engineering Ltd, an engineering consulting company.

The appointment and activities of the subcontracted company are managed through the application of the requirements of Clause 7.4, Purchasing. The project manager of CDH Construction Ltd oversees the design activities and is involved in design review meetings and design verification and validation activities. In addition, the project manager is responsible for ensuring that the design activities are carried out in accordance with the requirements of Clause 7.3 of ISO 9001:2000, Design and development. In this case, CDH Construction Ltd retains the responsibility for the design and is able to demonstrate that the management of subcontracted design is a part of its QMS.

SERVICE

AKP Corp. is a factory that manufactures electric motors. Traceability of the component parts of the product is not an internal requirement of this company. For a specific type of electric motor, however, one of their customers requires full traceability. In this specific case, AKP Corp.'s QMS has to apply the full requirements of Clause 7.5.2, Identification and traceability.

3. An Implementation Path

3.1 Accreditation

Accreditation bodies are usually connected to, or recognized by, their national government. Accreditation bodies accredit such organizations as registrars of QMS or EMS, certifiers of products, testing laboratories, standard developers, auditors and auditor training course providers. Some of the accreditation bodies accredit all of the above, but some confine themselves to a single subject. The Standards Council of Canada is Canada's accreditation body.

Accreditation: procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks [ISO Guide 2:1996, Clause 12.11]

In 1993, a group of accreditation bodies met in Houston and began an organization that is now named the International Accreditation Forum (IAF). The IAF was originally concerned with registration activities, but has recently begun to investigate other activities, such as product certification. The IAF has developed a peer evaluation process based on ISO/IEC Guide 61, and members (which are accreditation bodies) that met their criteria have signed a Multilateral Recognition Agreement with each other.

Each IAF member audits the registrars in accordance with ISO/IEC Guide 62, plus some additional IAF requirements for QMS. They are now in the process of auditing EMS registrars to ISO/IEC Guide 66, plus some additional IAF requirements.

3.2 Typical Project

3.2.1 Overview

Many organizations implement the ISO 9001 standard for immediate external benefits, which often include real or perceived market forces, the ability to bid for contracts (and the associated increase in market share), and a reduction in time-consuming customer audits. Other organizations see it as an opportunity to implement a disciplined process approach to management systems that incorporates a continual improvement approach. As outlined in ISO 9001, the process approach is the predominant practice in many nations and industry/economic sectors. The increasing use of QMS registration is a factor in the spread of this approach. In this approach, the organization initially implements a QMS in response to immediate demands by customers or possible stakeholders. As a result, the organization often benefits from significant improvements in product quality, cost, and internal operating activities. At the same time, or later, the organization may initiate a quality management effort to gain further improvements, building a more comprehensive QMS using ISO 9004:2000.

In the management-motivated approach, the organization's own management initiates the effort in anticipation of emerging marketplace needs and trends. In this route, ISO 9001:2000 and ISO 9004:2000 provide valuable insight in guiding a QMS's approach that will enhance the organization's quality achievement. The QMS implemented in this management-motivated approach will normally be more comprehensive and fruitful than the model used for demonstrating QMS adequacy.

It is important to recognize that implementing ISO 9001 is a major corporate project, and that the internal benefits of ISO 9001 implementation accrue over the longer term. An implementation path should be cognizant of both the time scales and the need to manage change.

A typical project approach involves the following phases, which are briefly discussed in Sections 3.2.2–3.2.9. (They are also illustrated in Figure 7):

- management decision and commitment;
- project planning and assignment of responsibility;
- training key resources;
- an initial assessment of the existing practices and procedures;
- documentation development;
- implementation of procedures;
- internal auditing or pre-assessment; and
- registration audit.

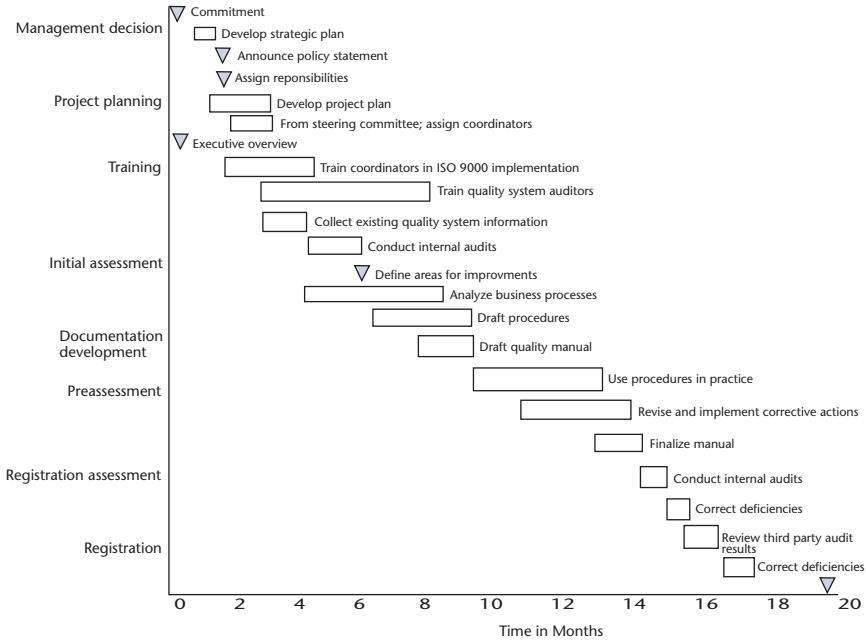


Figure 7
Typical Project Approach

Although registration is not necessarily a consequence of implementation, registration should be considered if

- required by a customer for a specific contract, or to be eligible as an approved vendor;
- viewed as a key requirement of market strategy; or
- perceived useful as a management support, through periodic external assessments.

When considering registration, it is important to keep the time scales in mind. Figure 8 shows the steps involved in a typical registration process. As shown, the steps involved are parallel to the implementation phases in Figure 7, and have a similar time scale. It is important to recognize that the time scale can be reduced substantially if management is truly committed, if the quality manual is prepared in advance, and if the company's internal auditors are trained.

3.2.2 Management Decision and Commitment

Top management leadership and involvement are essential in the strategic planning, project planning, and implementation phases. A business plan (or

equivalent) should be developed at the outset that meets the organization's strategy and

- defines the purpose of implementing ISO 9001;
- defines the objectives and constraints;
- defines the project deliverables in the process;
- identifies what resources are required (including human, material, and financial resources);
- identifies the overall costs; and
- determines project timing.

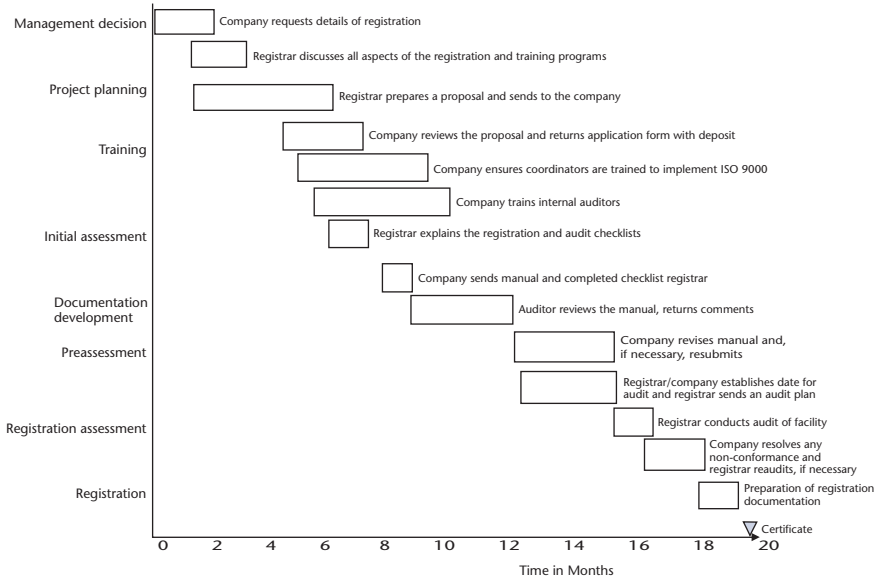


Figure 8
Typical Registration Process

A formal commitment to the QMS and stated objectives should be embodied in an overall policy statement on quality, signed by top management.

Through the implementation phase, senior management should

- drive the project's progress;
- determine actions that may be necessary to keep the project on track;
- determine actions to maximize all opportunities presented;
- identify lessons learned; and
- incorporate the changes, lessons learned, etc, into the continual improvement process.

3.2.3 Project Planning and Assignment of Responsibility

Since few organizations can afford to commit more than part-time resources, the timeline for implementing ISO 9001 standard should not be underestimated. The project plan should identify:

- the project milestones;
- who will be involved;
- how and when resources will be allocated; and
- how success will be measured.

3.2.4 Training Key Resources

At the start of ISO 9001 implementation, organizations usually have three distinct training needs. The first need is an executive overview of ISO 9001 at the strategic planning stage. The second need is a detailed understanding, on the part of the project leader and those coordinating the system development, of how the ISO 9001 requirements apply to each function within the organization. The third need is for internal auditors, who should be trained in the ISO 9001 requirements and how to conduct audits.

Many organizations achieve ISO 9001 implementation without outside resources. However, it may be useful at this point to establish a relationship with an experienced ISO 9001 facilitator and/or an accredited third-party registrar. An initial visit by a registrar is often useful for building an understanding of the registration process.

An experienced ISO 9000 facilitator can focus on the individual needs of a specific organization and provide a rapid transfer of knowledge. Some registrars, public education institutions, and private organizations offer generic and specialized training courses on the ISO 9000 family of standards, auditing, and documentation development. Training within this generic context can provide participants with access to a support network of organizations at a similar stage in the ISO 9000 implementation process.

3.2.5 Initial Internal Assessment

The initial assessment provides a starting point for benchmarking progress and helps focus on areas needing upgrade and improvement.

Every organization exists to accomplish value-adding work. The work is accomplished through a network of processes. The structure of the network is not usually a simple sequential structure; typically it is quite complex.

In an organization there are many functions to be performed. They include production, product design, technology management, marketing, training, human resources management, strategic planning, delivery, invoicing, and maintenance. Given the complexity of most organizations, it is important to

highlight the main processes and to simplify and prioritize processes for quality management purposes. In most cases, the secondary processes should also be identified.

An organization needs to identify, organize, and manage its network of processes and interfaces. The organization creates, improves, and makes consistent the quality of its offerings through the network of processes. This is a fundamental conceptual basis for the ISO 9000 family. Processes and their interfaces should be subject to analysis and continuous improvement.

3.2.6 Documentation Development

At this stage, all of the information related to the processes and their interrelationships should be collected. Much of this information will be found in system procedures, work instructions, job descriptions, operating instructions, memos, training manuals, policy documents, and the collective memory of the organization's personnel. Diagnostic and audit questions, highlighted by their respective icon (see the Preface), are provided throughout the following sections to help collect this information.

The organization must then decide what is to be documented, and in what type of format. ISO 9001 requires a minimum of specified documents, plus "documents needed by the organization to ensure the effective planning, operation and control of its processes" (see Clause 4.2.1(d)), and this broad statement implies a systematic approach to deciding which documents are needed. The ISO 9000 implementation effort is a good opportunity to make a critical review of the actual documentation, and improve it by adding, removing, or restructuring documents, so that it is best suited to the organization's objectives.

The preparation and use of documentation is intended to be a dynamic value-adding activity. Here are a few examples of how the preparation and the maintenance of documents, in whatever format, add value to an organization:

- training manuals or training software facilitate the integration of new employees, particularly in positions that rely heavily on the competence of personnel for a quality output;
- work instructions, whether work is production, service delivery, testing, calibration, or others, can be instrumental in consistently achieving planned results, particularly where the results of the work are critical to society, where it is important that many different people perform the same activity consistently, or where a complex activity cannot be reliably committed to memory;
- documents describing the processes (purpose, methods, equipment, resource requirements, etc) will facilitate internal audits by providing clear criteria for compliance and effectiveness of the processes;

- documents describing the relationships between processes (such as process maps) can be very useful in understanding and improving the flow of products and information and in showing how confidence in the quality of the final product is built into the processes; and
- system procedures developed to meet the requirements of the ISO 9001:1994.

Software products presently available on the market can help in the development and, to an even greater extent, in the maintenance of information, specifications, procedures and instructions, and records. As there are generic software products (or "suites") and software packages dedicated to QMS needs, an organization should assess which type is cost-effective and which software product is appropriate to the organization.

3.2.7 Implementation of Procedures

Translating the processes and procedure into actions may require time, as people may be slow to adjust to different ways of operating business and production processes. Sometimes the text of the procedure needs to be adjusted to reflect day-to-day practice. Other times, implementation involves perseverance and firmness. As the documentation work nears completion and improved practices are implemented, efforts should be directed to finalizing the system.

Maintaining the consistency of the processes and procedures that are deployed and implemented depends on a combination of the documentation and the skills and training of personnel. In each situation an appropriate balance between the extent of documentation and the extent of skills and training should be sought, so as to keep documentation to a reasonable level that can be maintained at appropriate intervals. QMS audits should be performed with this necessary balance in mind.

3.2.8 Internal Auditing or Pre-assessment

When the processes and procedures are finalized and implemented, an audit of the functions will identify problems not previously reported. The audit should be performed by a person trained in the auditing process and who has not been involved in developing the procedure being audited, and supervised by the person responsible for implementing the QMS.

When evaluating a QMS, these essential questions that have to be asked in relation to every process being evaluated:

- Are the processes defined and, where appropriate, are their procedures appropriately documented?
- Are the processes fully deployed and implemented as documented?
- Are the processes effective in providing the expected results?

- Is the resulting system robust enough to provide, on a continual basis, the information needed to improve the system and supply the product?

The answers to these questions, relating respectively to the approach, deployment, and results, will determine the outcome of the evaluation. An evaluation of a QMS may vary in scope and encompass a wide range of activities, some of which include management review and QMS audits.

3.2.9 Registration Audit

In the registration process, all applicable requirements of ISO 9001:2000 are subject to auditing. If any part of Clause 7 of ISO 9001:2000 is not applicable, this should be stated and justified in the quality manual, and brought to the attention of the registrar at the initial stage (see Clause 1.2 of ISO 9001:2000).

Audit: systematic, independent and documented **process** (3.4.1) for obtaining **audit evidence** (3.9.5) and evaluating it objectively to determine the extent to which **criteria** (3.9.4) are fulfilled (ISO 9000:2000, Clause 3.9.1)

The registrar selects auditors with industry-sector-specific knowledge and/or training, and in most cases an audit team is assigned. The auditing process is outlined in ISO 10011-1, *Guidelines for auditing QMS — Part 1: Auditing,* ISO 10011-2 on qualification criteria for QMS auditors, and ISO 10011-3 on the management of audit programs. It is planned that ISO 10011 will be replaced by ISO 19011 in 2002.

Once the organization's QMS is registered, the registrar is required to perform surveillance audits on a regular basis (usually annually or every six months). In a three-year cycle, all of the requirements of the standard must be audited.

It is important to inform the registrar in advance when a 9001 audit is to be combined with an audit to another management system such as ISO 14001 or ISO 13485. This enables the registrar to use the appropriate sector-specific auditors as early as the planning stage of the registration process, thereby reducing time and costs. The registrar selects auditors with industry-sector-specific knowledge and/or training, and in most cases an audit team is assigned.

The duration of the audit will depend upon such variables as exclusions (see Clause 1.2), size of the organization being audited, number of employees, etc. This is illustrated in Table 4.

Table 4
Typical Days to Carry Out an Audit vs Size of the Company Being Audited

Employees in company	Initial assessment (auditor days)		Annual surveillance visits (auditor days)		Reassessment visits (auditor days)	
	Total	On-site min.	Total	On-site min.	Total	On-site min.
Less than 5	2	1	1	0.5	1.5	1
5 – 9	2.5	1.5	1	0.5	1.5	1
10 – 19	3	2	1	1	2	1
20 – 29	4	2.5	1.5	1	3	2
30 – 59	6	4.5	2	1	4	2.5
60 – 100	7	5	2	1.5	4	3
101 – 250	8	6	2.5	2	5	3
251 – 500	10	7	3	2	6	4.5
501 – 1000	12	9	4	3	8	5.5
1001 – 2000	15	12	5	4	10	6.5
2001 – 4000	18	14	6	5	12	8
4001 – 8000	21	17	7	5	14	9

Typically, registrars work with an audit checklist. The checklist provides a consistent and unbiased basis for audits, based on one accepted interpretation of the standards, and ensures balanced coverage of the criteria. The availability of a checklist well in advance of the audit allows the auditee to have a shared understanding of what is to be assessed, in order to prepare for the audit.

In the actual audit, the auditor will answer the checklist questions, using one or more of the following techniques:

- inquiry, ie, asking questions, both formally and informally, and listening to the answers;
- observation, ie, collecting audit evidence through physical examination; and/or
- verification testing, ie, starting with final records and moving back to original documents.

3.3 Outside Assistance

3.3.1 Overview

When an organization decides to use the ISO 9000 series of standards for the first time, or wants to inquire about costs and benefits of such a decision, the organization usually needs some form of assistance from external sources. Much of that help is needed in the early stage of the project that leads to the registration of the QMS, but outside help can also be sought when an organization wants to use registration as a stepping stone towards a continuous quality improvement effort. One way to obtain this outside help is to hire personnel having appropriate knowledge and abilities. Other ways include subcontracted expertise and "free" support from associations, governmental agencies, and even Internet sites. The interpretation mechanism described in section 3.3.3 of this handbook is also available.

3.3.2 Acquiring Knowledge and Abilities

As the typical project described in section 3.2 shows, an organization needs to secure various types of information, knowledge, and abilities during the implementation and afterwards, in a continuous quality improvement effort. Information for adequate upper management awareness can be obtained through literature, formal awareness sessions, or conferences and public events sponsored by various associations and governmental agencies. Employee awareness is also an important component of the implementation process. This can be secured through formal lectures that would cover the basic concepts and mechanisms an organization needs for the implementation of its QMS. A classroom approach that invites the participant to actively contribute to the training process will often yield much better results, in terms of understanding and buy-in.

In-depth knowledge of the standards and the abilities to use them are better acquired through formal training courses that cover practical test cases. Employees who actively contribute to the QMS implementation effort within an organization need a few days of ISO 9000-related training. The implementation project manager needs a more thorough understanding, and this can possibly be acquired through, for example, a five-day auditor training course. The advantage of the five-day session is that it will provide the tools for the definition and implementation of the internal audits processes. Persons performing internal audits will need several days of training in order to acquire the necessary knowledge — including a good knowledge of ISO 9001 — and abilities to perform internal audits.

The awareness, information, and training are available from external sources, either public or private organizations. While outsourcing for adequate training, one should also look at other divisions or groups of the same organization, who

may have gone through an identical or similar project and may have training material and expertise.

3.3.3 Acquiring Expert Resources

3.3.3.1 General

With adequate training, an organization can use the ISO 9000 family of standards and achieve registration without further help. Often, however, organizations continue to rely on external resources for one or more of the following reasons:

- registration has to be achieved in a relatively short time, following customer or market pressures;
- the organization fears it might "fail" the registration audit;
- the organization apprehends the potential of making costly mistakes during the implementation;
- the organization wants access to a person with a very good knowledge of the standard; or
- there is a misunderstanding on the part of upper management, who believes that this is just another system that can be subcontracted or outsourced as a "turn-key" project.

External experts are often used for activities such as gap analysis, pre-audit, and implementation support.

3.3.3.2 Gap Analysis

This is an assessment of the organization's actual practices against the requirements of ISO 9001:2000; the exercise identifies the areas where the organization's QMS does not meet the requirements. Since this is done early in the process, this assessment should be carried out by an experienced, and possibly certified, auditor.

3.3.3.3 Pre-audit

Towards the end of the implementation effort, an organization may want its QMS assessed with the same rigour as a typical registration audit, in order to prepare for it. This is good practice for employees, as they will learn how to best interface with the auditors. It is also a good exercise to identify and correct any minor or major nonconformities before the registrar audit team shows up. The best resource for this pre-audit is an expert having experience performing registration audits.

3.3.3.4 Implementation Support

The extent of external support can range from a very occasional coaching to subcontracting the management and most of the activities for the entire project. When subcontracting many activities, care should be exercised:

a) Upper management and key personnel should take appropriate training before subcontracting, in order to understand what is involved in the implementation project, and after registration of the QMS.
b) The organization, and not the external expert, should decide on the orientations of the project, so that the resulting QMS is well-suited to the organization, and is effective and as efficient as possible.
c) A proper end-of-contract transition should be planned and performed, so that necessary activities do not fall between the cracks after the expert's departure. The transition plan should include the transfer of data, documents, and training material, as appropriate.

Here again, an expert may be available in another division or group of your organization. If you decide to go to an external expert, a few precautions are in order, as the consulting market always has "instant" experts with limited quality-related training and expertise. Some organizations have used a unique criterion in selecting their consultant: that the person be a certified auditor. That certainly provides confidence that the person knows the standard, but this knowledge alone may not be sufficient for all types of consulting work. The main criterion should be past experience in doing work similar to the type of support needed. For example, a good "coaching" expert may not be a good project manager, and vice-versa.

3.3.4 Interpretations

Q/A

During the past few years, difficulties in interpreting the ISO 9001:1994 standard led the international community to develop a formal interpretation mechanism. This will prove useful because of its worldwide application, including people of different cultures, speaking different languages, using translated versions of the standard. Experience has shown that a difference in interpretation may arise between two persons of the same organization, between an organization and its customers or, as occurs most often, between an organization and its registrar.

One reliable source of supplementary information is the Product Introduction Package modules published by ISO/TC 176, each on a specific subject related to the ISO 9000:2000 family. The Product Introduction Packages modules available at the time of this handbook's publication. When these documents do not provide enough information to answer a question, then one should use the formal international interpretations process.

The ISO/TC 176 has structured this process to receive, resolve, and answer requests for interpretations, within a reasonable timeframe.

Requests for interpretation are received by the Secretariat of the Canadian Advisory Committee to the ISO/TC 176. Requests can be made by letter, fax, or e-mail.

3.3.5 Internal Audits

To properly manage an organization, managers must have access to factual, reliable information, as is suggested by the quality management principle "Factual approach to decision-making" described in section 2.1 of this handbook. To a large extent, this factual and reliable information comes from the monitoring and the measurement of the products, of the processes, and of the QMS. ISO 9001:2000 addresses this in Clause 8.2:

- 8.2.4, Monitoring and measurement of product;
- 8.2.3, Monitoring and measurement of processes;
- 8.2.2, Internal audit.

Internal auditing is the tool for measuring the QMS. This is different in many ways from the measurement of products and processes, and this section only focusses on the unique aspects related to internal audits.

Internal audits should look at individual processes within the QMS, question their compliance to the audit criteria, and assess their effectiveness in achieving the desired results. This implies that

a) The scheduling of internal audits needs to be only remotely related to the external audits schedule.
b) The preparation, performance, and reporting of the internal audit will be specific to the process(es) audited.
c) More resources will be allocated to internal auditing than on external auditing.

audit:
systematic, independent and documented **process** (3.4.1) for obtaining **audit evidence** (3.9.4) and evaluating it objectively to determine the extent to which **audit criteria** (3.9.3) are fulfilled
[ISO 9000, 3.9.1]

audit conclusion:
outcome of an **audit** (3.9.1) provided by the **audit team** (3.9.10) after consideration of the audit objectives and all **audit findings** (3.9.5)
[ISO 9000, 3.9.6]

audit evidence:
records (3.7.6), statements of fact or other **information** (3.7.1) which are relevant to the **audit criteria** (3.9.3) and verifiable
NOTE Audit evidence can be qualitative or quantitative.
[ISO 9000, 3.9.4]

audit findings:
results of the evaluation of the collected **audit evidence** (3.9.4) against **audit criteria** (3.9.3)
[ISO 9000, 3.9.5]

audit team:
one or more **auditors** (3.9.9) conducting an **audit** (3.9.1)
NOTE 1 One auditor in the audit team is generally appointed as audit team leader.

NOTE 2 The audit team can include auditors-in-training and, where required, **technical experts** (3.9.11).
NOTE 3 Observers can accompany the audit team but do not act as part of it.
[ISO 9000, 3.9.10]

3.3.6 Usefulness of Audit Conclusions

If internal audit scheduling is adequately influenced by the status and importance of the processes and areas (see Clause 8.2.2), the audit results are more likely to be of value to managers. Internal audits deliver two types of results:

a) The conclusions of each individual audit, including any necessary corrective action; this includes any audit done with the sole purpose of verifying the proper implementation of a corrective action.
b) The above information can be analyzed to give information on the effectiveness of the audit processes itself. For example, these analyses can be performed on
   1. the adequacy of corrective actions;
   2. the distribution of corrective actions between departments;
   3. the timeliness of the implementation of corrective actions; and
   4. organizational deficiencies common to many processes.

These audit results will only be useful if they are factual and placed in a proper context. When deciding on audit findings and audit conclusions, an audit team should avoid anecdotal information, and describe the findings and conclusions in their context. Likewise, the results of the analyses referred to in item 2 above should be presented in a factual manner, to enable the managers to assess their significance.

3.3.7 Measuring and Monitoring the Audit Processes

Internal audit processes are part of the QMS; as such, their compliance and effectiveness should be regularly assessed. This is easily done whether the internal audit processes are in response to an external standard (ISO 9001:2000) or are developed by the organization itself. Compliance with the external standard can be assessed initially, and subsequently, when the audit processes change. Compliance to the defined methods can be assessed by a person who is not usually involved in internal auditing. But assessing the effectiveness of the internal audit processes is all together different.

One purpose of the internal audit processes is to assess the effectiveness of other processes. Can the internal audit processes be used for an assessment of their own effectiveness? No, for the same reason that an instrument can not be calibrated using itself as the basis for calibration.

Measuring the effectiveness of the internal audit processes obviously requires other tools and methods. Each organization should define performance indicators for the internal audit processes. These indicators can measure auditor performance, auditee responsiveness, and other system indicators. Good literature is available on this subject, and it should be consulted when the internal audit processes reach a certain level of maturity.

3.4 Scope, References, and Definitions of ISO 9001:2000

1. Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and
b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

In the Scope, the notion of consistently providing products that meet customer and regulatory requirements is highlighted, and the need for continuous improvement of the QMS is clarified. Enhancing customer satisfaction is also an aim, over and above providing conforming products. The notion of continual improvement is introduced here, as it will unfold throughout the standard.

For more information on Clause 1.2 as it relates to exclusions, refer to the examples of exclusions in section 2.4 of this handbook, to the guidance under the

continual improvement: recurring activity to increase the ability to fulfill **requirements** (3.1.2)
[ISO 9000, 3.2.13]

customer satisfaction: customer's perception of the degree to which the customer's

Service icon in section 7.3.1, and reference to the PIP on application.

requirements (3.1.2) have been fulfilled [ISO 9000, 3.1.4]

requirement: need or expectation that is stated, generally implied or obligatory [ISO 9000, 3.1.2]

1) Have any requirements of the standard been excluded from the scope of application of the QMS?

2) If there are any exclusions claimed, are these exclusions limited to the requirements within Clause 7 of the standard?

3) Do any of the exclusions claimed affect the organization's ability, or responsibility, to provide product that fulfills customer requirements and applicable regulatory requirements?

2. Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary.*

3. Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier ===> organization ===> customer

The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”.

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

In developing the year 2000 revisions of the ISO 9000 family of Standards, and to assist in their readability and translation, great care has been taken to use the correct English words and terms to describe the concepts and requirements. The objective is to use simple, technically accurate terms, and to rely, to the greatest extent possible, on common dictionary definitions. As with most technical subjects, some terms have very specific meanings that

customer: **organization** (3.3.1) or person that receives a **product** (3.4.2) [ISO 9000, 3.3.5]

organization: group of people and facilities with an

are different from their commonly used dictionary definitions. In all other cases, common dictionary definitions are used. Definitions of terms in ISO 9000:2000 have normative status, and take precedence over the terms' common dictionary definitions. These normative definitions are included in Appendix B. For more information, see the reference to the PIP on terminology.

An example is the definition of the term "product" that is found ISO 9000:2000 (reproduced in Appendix B). Note 1 of the definition of "product" clearly states

> There are four generic product categories, as follows:
> — services (e.g. transport);
> — software (e.g. computer program, dictionary);
> — hardware (e.g. engine mechanical part);
> — processed materials (e.g. lubricant).
>
> Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example the offered product "automobile" consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).
>
> See too the other notes in the same definition.

Organizations are encouraged to also adopt the ISO 9000:2000 vocabulary in all their activities.

arrangement of responsibilities, authorities and relationships [ISO 9000, 3.3.1]

supplier: **organization** (3.3.1) or person that provides a **product** (3.4.2) [ISO 9000, 3.3.6]

☐ Should we use the vocabulary of ISO 9000:2000 within our organization?

4. Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),
b) determine the sequence and interaction of these processes,
c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
e) monitor, measure and analyze these processes, and
f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

Organizations wishing to adapt an existing QMS

An organization with an existing QMS should not need to rewrite its documentation in order to meet the requirements of ISO 9001:2000. This is particularly true if an organization has structured its QMS according to the way it effectively operates, using a process approach. In this case, the existing documentation may be adequate and can be simply referenced in the revised quality manual.

An organization that has not used a process approach in the past will need to pay particular attention to the definition of its processes, their sequence, and their

quality management system:
management system (3.2.2) to direct and control an **organization** (3.3.1) with regard to **quality** (3.1.1)
[ISO 9000, 3.2.3]

effectiveness:
extent to which planned activities are realized

interaction, and it may be appropriate to document these as process maps. It must be emphasized, however, that documented process maps are not a requirement of ISO 9001:2000.

Because the documentation requirements in ISO 9001:2000 are less prescriptive than those in the 1994 edition, an organization may be able to carry out some streamlining and/or consolidation of existing documents, in order increase the correlation between its documentation system and the actual business processes.

Organizations using ISO 9001:2000 for the first time

Organizations using ISO 9001:2000 for the first time to improve a QMS or to have it registered must understand that the new ISO 9001:2000 emphasizes a process approach. This requires

- identifying the processes necessary for the effective implementation of the QMS;
- understanding the interactions between these processes; and
- documenting the processes to the extent necessary to assure their effective operation and control.

These processes include the management, resource, product realization, and measurement processes that are relevant to the effective operation of the QMS. Analysis of the processes should be the driving force for defining the amount of documentation needed for the QMS, taking into account the requirements of ISO 9001:2000. It should not be the documentation that drives the processes.

1) Has the organization established, documented, implemented, and maintained a QMS?

2) Has the organization continually improved the effectiveness of the QMS?

3) Has the organization

   a) identified the processes needed for the QMS and their application throughout the organization?

and planned results achieved
[ISO 9000, 3.2.14]

process:
set of interrelated or interacting activities which transforms inputs into outputs
NOTE 1 Inputs to a process are generally outputs of other processes.
NOTE 2 Processes in an **organization** (3.3.1) are generally planned and carried out under controlled conditions to add value.
NOTE 3 A process where the **conformity** (3.6.1) of the resulting **product** (3.4.2) cannot be readily or economically verified is frequently referred to as a "special process".
[ISO 9000, 3.4.1]

☐ Who is responsible for the overview of the project related to the documenting, implementing, and maintaining the QMS?

☐ Have the processes been identified and documented as necessary?

☐ Has the sequence and interaction been established and documented (see quality plan)?

☐ Who is responsible for establishing the effectiveness of these processes?

(Note: Processes needed should include processes for management activities, provision of resources, product realization, and measurement.)

b) determined the sequence and interaction of these processes?

c) determined criteria and methods needed to ensure that both the operation and control of these processes are effective?

d) ensured the availability of resources and information necessary to support the operation and monitoring of these processes?

e) monitored, measured, and analyzed these processes?

f) implemented actions necessary to achieve planned results and continual improvement of these processes?

☐ Are resources available to monitor, measure where applicable, and analyze these processes?

☐ Who is responsible for the continual improvement of the system?

☐ Have outsourced processes been identified and considered?

4) Are these processes managed in accordance with the requirements of the standard?

5) a) Does the organization outsource (sub-contract) any process that has been identified as "necessary for the effective implementation of the QMS"?

b) If yes, does the organization ensure control over any such outsourced processes?

c) Is the control of such outsourced processes identified within the QMS?

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include
a) documented statements of a quality policy and quality objectives,
b) a quality manual,
c) documented procedures required by this International Standard,
d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and
e) quality records required by this International Standard (see 4.2.4).

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.
NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to
a) the size of organization and type of activities,
b) the complexity of processes and their interactions, and
c) the competence of personnel.
NOTE 3 The documentation can be in any form or type of medium.

Figure 9 illustrates the relationship between the different documents found in a QMS, and how documents and records differ. The medium used can be paper, magnetic, electronic, or optical computer disc, photograph or master sample, or a combination thereof.

document:
information (3.7.1) and its supporting medium
[ISO 9000, 3.7.2]

procedure:
specified way to carry out an activity or a **process** (3.4.1)
NOTE 1 Procedures can be documented or not.
NOTE 2 When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used. The **document** (3.7.2) that contains a procedure can be called a "procedure document".
[ISO 9000, 3.4.5]

The ISO/TC 176 prepared a set of guidelines called the *Product Introduction Package,* which contains numerous modules. The following is an excerpt from the draft module "Guidance on the Documentation Requirements of ISO 9001:2000":

ISO 9001:2000 allows an organization flexibility in the way it chooses to document its QMS. This enables an organization to develop the minimum amount of documentation needed in order to demonstrate the effective planning, operation, and control of its processes and the implementation and continual improvement of its QMS. It must be stressed that ISO 9001:2000 requires a "documented QMS" and not a "system of documents".

Figure 9
QMS Documentation

Provided by Accademia Qualitas

Requirements for Documentation

Clause 4.1 of ISO 9001:2000, "General Requirements", requires an organization to "establish, document, implement, maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard".

Clause 4.2.1, "Documentation requirements", requires that the QMS documentation include

a) documented statements of a quality policy and quality objectives (see 5.3 and 5.4)
b) a quality manual (see 4.2.2)
c) documented procedures required by the standard
d) documents required by the organization to ensure the effective planning, operation, and control of its processes
e) quality records required by the standard.

The notes after Clause 4.2 make it clear that where the standard specifically requires a "documented procedure", the procedure has to be established, documented, implemented, and maintained. It also emphasizes that the extent of the QMS documentation may differ from one organization to another, due to

- size of organization and type of activities;
- complexity of processes and their interactions; and
- competence of personnel.

ISO 9001:2000 specifically requires the organization to have "documented procedures" for the following six activities:

- 4.2.3 Control of documents
- 4.2.4 Control of quality records
- 8.2.2 Internal audit
- 8.3 Control of nonconformity
- 8.5.2 Corrective action
- 8.5.3 Preventive action

Some organizations (particularly larger organizations, or those with more complex processes) may require additional documented procedures in order to implement an effective QMS.

quality manual:
document (3.7.2) specifying the **quality management system** (3.2.3) of an **organization** (3.3.1)
NOTE Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.
[ISO 9000, 3.7.4]

quality plan:
document (3.7.2) specifying which **procedures** (3.4.5) and associated resources shall be applied by whom and when to a specific **project** (3.4.3), **product** (3.4.2), **process** (3.4.1) or contract
NOTE 1 These procedures generally include those referring to quality management processes and to product realization processes.
NOTE 2 A quality plan often makes reference to parts of the **quality manual** (3.7.4) or to procedure documents.
NOTE 3 A quality plan is generally one of the results of **quality planning** (3.2.9).
[ISO 9000, 3.7.5]

record:
document (3.7.2) stating results achieved or providing evidence of activities performed
NOTE 1 Records can be used, for example, to document **traceability** (3.5.4) and to provide evidence of

Other organizations may require additional procedures, but the size and/or culture of the organization could enable these to be effectively implemented without necessarily being documented.

In order to demonstrate compliance with ISO 9001:2000, however, the organization must be able to provide objective evidence that its QMS has been effectively implemented.

All the documents that form part of the QMS must be controlled in accordance with Clause 4.2.3 of ISO 9001:2000, or, for the particular case of records, according to Clause 4.2.4.

action (3.6.4) and **corrective action** (3.6.5).
NOTE 2 Generally records need not be under revision control.
[ISO 9000, 3.7.6]

specification: document (3.7.2) stating **requirements** (3.1.2)
NOTE A specification can be related to activities (eg, procedure document, process specification, and test specification), or **products** (3.4.2) (eg, product specification, performance specification, and drawing).
[ISO 9000, 3.7.3]

Quality Policy and Objectives

Requirements for the quality policy and quality objectives are defined in Clauses 5.3 and 5.4.1. Because the quality policy is a document, it must be controlled according to the requirements of Clause 4.2.3. Some organizations that may be revising their quality policy for the first time, in order to meet ISO 9001:2000, will need to pay particular attention to items c), d), and g) of Clause 4.2.3.

☐ Who is responsible for ensuring that the quality manual includes the documented procedures, the interaction between the processes?

☐ Have we documented our quality policy and quality objectives?

Documents

The organization requires documents to ensure the effective planning, operation and control of its processes. In order for an organization to demonstrate the effective implementation of its QMS, it may be necessary to develop documents other than documented procedures. However, the only documents specifically mentioned in ISO 9001:2000 are

- quality policy (Clause 4.2.1 a);
- quality objectives (Clause 4.2.1 a); and
- quality manual (Clause 4.2.1 b).

There are several instances in ISO 9001:2000 where an organization could add value to its QMS and demonstrate conformity by the preparation of other documents, even though the standard does not specifically require them. Examples include

- process maps;

☐ Have we systematically establish which documents are needed to effectively plan, operate and control, and measure and monitor processes and products?

☐ For these needed documents, have we defined a structure that will facilitate their maintenance?

- organization charts;
- internal communications;
- various schedules (production, audit, etc);
- product specifications;
- approved supplier lists;
- quality plans;
- product catalogues; and
- Web site contents.

Demonstrating Compliance with ISO 9001:2000

In order to claim conformity with ISO 9001:2000, the organization must provide objective evidence of the effectiveness of its processes and its QMS. This evidence may not necessarily consist of documents or records, except where specifically mentioned in ISO 9001:2000. In many cases, by pointing to or showing results of activities, organizations (and in particular small organizations) may be able to demonstrate compliance without the need for extensive documentation.

1) Does the QMS documentation include

a) documented statements of a quality policy (see Clause 5.3) and quality objectives (see Clause 5.4.1)?

b) a quality manual (see Clause 4.2.2)?

b) documented procedures required by this standard (see Clauses 4.2.3, 4.2.4, 8.2.2, 8.3, 8.5.2, and 8.5.3)?

c) other documents needed by the organization to ensure the effective planning, operation and control of its processes? (Although not specifically required by the standard, such documents may include process maps, organization charts, internal communications, production schedules, approved supplier lists, and quality plans.)

e) quality records required by this standard (see Clauses 5.6.1, 6.2.2 e), 7.1 d), 7.2.2, 7.3.2, 7.3.4, 7.3.5, 7.3.6, 7.3.7, 7.4.1, 7.5.2 d), 7.5.3, 7.5.4, 7.6 a), 7.6 (validity of previous measuring results when the equipment is found not to conform to requirements, and results of calibration and verification), 8.2.2, 8.2.4, 8.3, 8.5.2, and 8.5.3)?

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),
b) the documented procedures established for the quality management system, or reference to them, and
c) a description of the interaction between the processes of the quality management system.

The implementation of a QMS by an organization is most effective when individuals in the organization understand its intention, know how it functions in particular in the area of their responsibility, and perceive its interface with other parts of the system. The quality manual has an important role in this regard for both internal and external parties.

quality manual: document (3.7.2) specifying the **quality management system** (3.2.3) of an **organization** (3.3.1) [ISO 9000, 3.7.4]

The quality manual could be one document supported by several levels of other documents, each level becoming progressively more detailed. There might also be an overall system manual, one or more specific procedural manuals, work instructions, and reference documents. Together, these documents define the QMS. Further guidance on the development of quality manuals is given in ISO 10013.

☐ Do the procedures describe the purpose, scope, responsibility, and the full details of how, what, when, and where activities are performed?

☐ Are the forms described in the quality system included or referenced in the procedures?

Clause 4.2.2 specifies the minimum content for a quality manual. The format of the manual is a decision for each organization, and will depend on the organization's size, culture, and complexity.

A small organization may find it appropriate to include the description of its entire QMS within a single manual, including all the documented procedures required by the standard. Large multinational organizations may need several manuals at the global, national, or regional level, and a more complex hierarchy of documentation.

1) Has the organization established and maintained a quality manual that includes

a) the scope of the QMS, including details of and justification for any exclusions?
b) the documented procedures established for the QMS, or reference to them?
c) a description of the interaction between the various processes of the QMS?

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed
a) to approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified,
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,
f) to ensure that documents of external origin are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Where applicable, controlled documents should include the following information: title, reference number, date issued and date effective, revision level, review date or review frequency, revision history, author, approved by, distribution list, pagination, and computer file references.

The organization's system should provide a clear and precise control of procedures and responsibilities for approval, issue, distribution, and administration of internal and external documentation, including the

document: information (3.7.1) and its supporting medium
[ISO 9000, 3.7.2]

information: meaningful data
[ISO 9000, 3.7.1]

removal or identification of obsolete documents (to prevent misuse). This can be accomplished, for example, by making the documentation available on a central computer system, or by maintaining a master list of documents or data that records their level of approval, distribution (location of copies), and revision status.

Applicable documents must be accessible in the relevant places of work.

When retained, obsolete or superseded controlled documents should be clearly marked or kept in a secure location, and other copies should be disposed of. It may be possible to maintain detailed records of changes as they are made, rather than retaining actual copies of each issue of every document.

Where document control is achieved by electronic means, special attention should be given to methods for identifying appropriate approval of electronic copies, access, security, distribution, media, backup, and archiving procedures.

1) Are the documents required by the QMS controlled (see Clause 4.2.1)?

2) Are the quality records (see 4.2.1 e)) controlled according to the requirements given in Clause 4.2.4?

3) Has the organization established a documented procedure for the control of documents?

4) Does this documented procedure define the controls needed to
   a) approve documents for adequacy prior to issue?
   b) review, update as necessary, and reapprove documents?
   c) ensure that changes and the current revision of the document are identified?
   d) ensure that relevant versions of applicable documents are available at points of use?
   e) ensure that documents remain legible and readily identifiable?

procedure:
specified way to carry out an activity or a **process** (3.4.1)
NOTE 1 Procedures can be documented or not.
NOTE 2 When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used. The **document** (3.7.2) that contains a procedure can be called a "procedure document".
[ISO 9000, 3.4.5]

☐ Is there a documented procedure for the control of documents?

☐ Who is responsible for document control within the design group, quality assurance, purchasing, production, servicing, etc?

☐ Does the scope of the documented procedure for the control of documents cover the relevant document categories, eg, quality manual and system procedures, design documents, quality plans, process control documents, calibration procedures, and audit documentation?

☐ Who is responsible for controlling external documents?

f) ensure that documents of external origin are identified, and their distribution controlled?
g) prevent the unintended use of obsolete documents, and apply suitable identification to them if they are retained for any purpose?

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

The organization's quality records should give evidence that QMS elements falling within the requirements of ISO 9001:2000 have been effectively implemented, and that the planned results were achieved.

ISO 9001:2000 does not specify a minimum time period for the retention of quality records. In some circumstances it may be the organization's responsibility to verify their requirements with regulatory authorities. Aspects of product liability and the legality of various forms of record-keeping should be taken into consideration. If time periods are not prescribed by legislation or in the contract, the organization may consider the expected lifetime of the product and document appropriate retention times accordingly. Records may be disposed of after the specified retention period.

A number of clauses throughout ISO 9001:2000 require that records be maintained in accordance with Clause 4.2.4. The records that must be kept to satisfy ISO 9001:2000 are set out in Table 5.

record:
document (3.7.2) stating results achieved or providing evidence of activities performed
NOTE 1 Records can be used, for example, to document **traceability** (3.5.4) and to provide evidence of **verification** (3.8.4), **preventive action** (3.6.4) and **corrective action** (3.6.5).
NOTE 2 Generally records need not be under revision control.
[ISO 9000, 3.7.6]

☐ Which type of records are identified as necessary in our "record documentation procedure"?

☐ Which departments are responsible for

Table 5
Examples of Quality Records

Clause	Record required
5.6.1	Management review
6.2.2 e)	Education, training, skills, and experience
7.1 d)	Evidence that the realization processes and resulting product fulfill requirements
7.2.2	Results of the review of requirements relating to product and actions arising from the review
7.3.2	Design and development inputs
7.3.4	Results of design and development reviews and any necessary actions
7.3.5	Results of design and development verification and any necessary actions
7.3.6	Results of design and development validation and any necessary actions
7.3.7	Results of the review of design and development changes and any necessary actions
7.4.1	Results of supplier evaluations and actions arising from the evaluations
7.5.2 d)	Records required by the organization to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement
7.5.3	The unique identification of the product, where traceability is a requirement
7.5.4	Customer property that is lost, damaged, or otherwise found to be unsuitable for use
7.6 a)	Standards used for calibration or verification of measuring equipment where no international or national measurement standards exist
7.6	Validity of previous results when measuring equipment is found not to conform with its requirements
7.6	Result of calibration and verification of measuring equipment
8.2.2	Internal audit results

collecting and storing the records?

☐ What forms of media are records stored in?

☐ How long will the records be retained?

☐ In which locations are records stored?

☐ What environment will be suitable?

☐ Are records that are required to be destroyed after a period of time identified?

☐ How long will the records be retained?

8.2.4	Evidence of product conformity with the acceptance criteria and indication of the authority responsible for the release of the product
8.3	Nature of the product nonconformities and any subsequent actions taken, including concession obtained
8.5.2	Results of corrective action
8.5.3	Results of preventive action

Organizations may develop other records that are needed to demonstrate conformity of their processes, products, and QMS.

Records should be prepared, stored safely, protected from unauthorized access, protected from alteration, and maintained by the organization. Records should be properly identified, collected, indexed, and filed, and be readily accessible as and where needed. They may be stored or copied in any suitable form, for example, hard copy, microfilm, or electronic media. Where records are held on electronic media, consideration of the retention times and accessibility of the records should take into account the rate of degradation of the electronic images and the availability of the devices and software needed to access the records. Such copies of records should contain all the relevant information in the original records.

1) Has the organization established records to provide evidence of conformity to requirements and of the effective operation of the QMS? (See Clause 4.2.1 e).)

2) Are the records legible, readily identifiable and retrievable?

3) Has the organization established a documented procedure to define the control of quality records?

4) Does this documented procedure define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?

5. Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
b) establishing the quality policy,
c) ensuring that quality objectives are established,
d) conducting management reviews, and
e) ensuring the availability of resources.

Consideration needs to be given by top management to the identification and provision of resources adequate to implement the QMS's quality policy and achieve its objectives, as well as to satisfy customers' and other requirements. This consideration should cover all processes identified pursuant to Clause 4.1.

1) Has the organization's top management provided evidence of its commitment to the development and implementation of the QMS and to continually improve its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements?
b) establishing the quality policy?
c) ensuring that quality objectives are established?
d) conducting management reviews?
e) ensuring the availability of resources?

top management: person or group of people who directs and controls an organization (3.3.1) at the highest level [ISO 9000, 3.2.7]

☐ How has top management demonstrated its commitment to developing, implementing and continually improving its QMS?

☐ Has top management informed people in the organization of the importance of meeting customer, statutory, and regulatory requirements?

☐ Is the quality policy known to people in the organization, and do staff know of their respective objectives and how their

accomplishments will be measured?

☐ Have resource requirements been planned and made available to meet the needs of the QMS activities?

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

It is important to thoroughly understand the customer needs and expectations, which will be incorporated in the product's stated, generally implied or obligatory needs or expectations (ie, requirements, as per Clause 3.1.2 of ISO 9000). For certain types of products, these requirements can be stated on a label, as a service level (number of stars for a hotel), etc. See too Clause 7.2, which deals with customer-related processes, and to Clauses 5.1 a) and 5.5.2 c), which deal with employee awareness.

1) Has top management ensured that customer requirements are determined and are met with the aim of enhancing customer satisfaction?

customer:
organization (3.3.1) or person that receives a product (3.4.2)
[ISO 9000, 3.3.5]

customer satisfaction:
customer's perception of the degree to which the customer's **requirements (3.1.2)** have been fulfilled
[ISO 9000, 3.1.4]

requirement:
need or expectation that is stated, generally implied or obligatory
[ISO 9000, 3.1.2]

☐ How has top management focused on customer requirements?

☐ Are the people in the organization aware of the focus?

5.3 Quality policy

Top management shall ensure that the quality policy
a) is appropriate to the purpose of the organization,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization, and
e) is reviewed for continuing suitability.

Top management is required to develop and define the quality policy, which should be published throughout the organization and be seen to be fully supported by the management. Employees, including newly hired, part-time and temporary employees, should be trained to understand the objectives of the organization and the commitment required to achieve these objectives. The policy should be expressed in language that is easy to understand, and the quality objectives should be measurable, achievable, planned and periodically reviewed.

quality policy: overall intentions and direction of an **organization** (3.3.1) related to **quality** (3.1.1) as formally expressed by **top management** (3.2.7) [ISO 9000, 3.2.4]

Top management should continuously demonstrate visible commitment to the quality policy by activities that may include, but are not limited to, the following:

- ensuring that the organization's personnel understand and implement the quality policy;
- initiating, managing, and following up on the implementation of the quality policy, including implementation and maintenance of the QMS;
- not accepting deviations from the quality policy in any part or aspect of the organization; and
- providing adequate resources and training to support QMS development and implementation.

☐ Is the quality policy known by affected personnel and is it appropriate?

☐ Is there a regular review of the quality policy?

1) Has top management ensured that the quality policy

   a) is appropriate to the purpose of the organization?

b) includes a commitment to comply with requirements, and a commitment to continually improve the effectiveness of the QMS?
c) provides a framework for establishing and reviewing quality objectives?
d) is communicated and understood within the organization?
e) is reviewed for continuing suitability?

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that
a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

The quality policy "provides a framework for establishing and reviewing quality objectives" (Clause 5.3). The corollary is that the quality objectives need to be consistent with the quality policy. Beyond that, it is required that measurable quality objectives be established at many levels, from the corporate level through departments and functions, as well as those needed to meet product requirements. In addition to product-related objectives, quality objectives may also be set for processes, as well as for parts of the QMS. They can be related to QMS effectiveness, customer satisfaction, process capability, qualification of personnel, AQL (acceptable quality level

quality objective: something sought, or aimed for, related to **quality** (3.1.1) [ISO 9000, 3.2.5]

☐ How are the quality objectives established for all functions and levels?

or acceptance quality level; see ISO 3435-2), or per cent defective products, etc.

☐ Are they measurable, and have they been implemented?

Once the objectives have been established, the organization must plan its activities and resources to meet those objectives. ISO 9001:2000 has three clauses related to planning:

☐ Who is responsible for the planning of the QMS, and does this planning include reviewing any changes and their effects?

- Clause 5.4.2, on the planning of the QMS itself;
- Clause 7.1, on the planning of product realization; and
- Clause 8.1, on the planning of measurement, analysis, and improvement processes.

Clause 5.4.2 obviously applies to the initial effort of planning the QMS, but it applies equally to all changes in the QMS, from a small incremental change to drastic re-engineering.

1) Has the organization's top management ensured that quality objectives are established at relevant functions and levels within the organization?

2) Do the established quality objectives include those needed to meet requirements for product?

3) Are the quality objectives measurable?

4) Are the quality objectives consistent with the quality policy?

5) Has top management ensured that
   a) the planning of the QMS is carried out in order to meet the requirements given in Clause 4.1 of ISO 9001:2000?
   b) the planning of the QMS is carried out in order to meet the quality objectives?
   c) the integrity of the QMS is maintained when changes to the QMS are planned and implemented?

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,
b) reporting to top management on the performance of the quality management system and any need for improvement, and
c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

Top management shall ensure that appropriate communication channels are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

In an organization, employees need to know their responsibilities and authorities, and how these relate to those of other employees or other groups. This can be very simple in organizations that have only a few employees, but in larger organizations the relationships usually have to be presented more formally, through descriptions, charts, or matrices, as appropriate.

One of the key positions related to the QMS is that of the management representative. Within the organization, one person (or many) will be delegated responsibility and authority to oversee the effective working of the QMS. A management representative is required to be appointed by top management. The management representative may be totally devoted to quality

☐ How have the responsibilities and authorities been communicated?

☐ Who is the management representative?

☐ Is this known throughout the organization?

management system activities, or conduct them in conjunction with other activities within the organization. The management representative should have sufficient authority to ensure that the needed processes are established, implemented, and maintained throughout the organization, to report to top management on the performance and needed improvement, and to ensure the promotion of customer awareness throughout the organization. The latter responsibility is closely related to Clause 5.1 a), on top management communication.

☐ Is the effectiveness of the operation known throughout the organization?

Very often, the role of the management representative will include internal communication, as well as external communication with customers, suppliers, and regulatory bodies on matters related to the QMS.

1) Has top management ensured that the responsibilities, authorities, and their interrelation are defined and communicated within the organization?

2) Has top management appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes
   a) ensuring that processes needed for the QMS are established, implemented, and maintained?
   b) reporting to top management on the performance of the QMS and any need for improvement?
   c) ensuring the promotion of awareness of customer requirements throughout the organization?

3) Has top management ensured that appropriate communication processes are established within the organization, and that communication takes place regarding the effectiveness of the QMS?

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained.

5.6.2 Review input

The input to management review shall include information on
a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system, and
g) recommendations for improvement.

5.6.3 Review output

The output from the management review shall include any decisions and actions related to
a) improvement of the effectiveness of the quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.

The organization's top management should review the QMS. The intervals between reviews should be carefully planned and periodically assessed to ensure the continuing suitability, adequacy, and effectiveness of the QMS. The management review process, frequency, and levels of inputs will depend on the individual circumstances. Some organizations have found that annual management reviews are acceptable, while others conduct them on a quarterly basis.

review:
activity undertaken to determine the suitability, adequacy and **effectiveness** (3.2.14) of the subject matter to achieve established objectives [ISO 9000, 3.8.7]

Inputs to management reviews may include, but are not limited to the following:

- the adequacy of the organizational structure, including its staffing and other resources;
- conformity to ISO 9001:2000 and the effective implementation of the QMS;
- compliance with quality policy; and
- information based on customer feedback, internal feedback (such as results of internal audits), process performance, and product performance, as well as corrective and preventive actions taken.

Management should focus on trends that may indicate problems. Chronic problem areas should receive special attention. Actions that the management review determines to be required by changes to the QMS should be implemented in a timely manner. The effectiveness of any changes should be evaluated.

Management reviews are conducted in addition to, and use the findings of, internal quality audits (see Clause 8.2.2), which are conducted to ensure continued adherence to the system. Both management reviews and internal audits should be performed regularly, and not be conducted only as a reaction to the identification of quality problems.

1) Has top management reviewed the organization's QMS, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness?

2) Does the review include

   a) assessing opportunities for improvement?
   b) assessing the need for changes to the QMS?
   c) assessing the need for changes to the quality policy?
   d) assessing the need for changes to quality objectives?

3) Do the inputs to management review include information on

   a) results of audits;

☐ Who is responsible for conducting the management review?

☐ Who are the regular participants?

☐ Are the reviews scheduled?

☐ How are the reviews documented?

☐ What information and records are reviewed?

☐ How are the suitability, adequacy, and effectiveness of the QMS evaluated?

b) customer feedback;
c) process performance and product conformity;
d) status of preventive and corrective actions;
e) follow-up actions from previous management reviews;
f) planned changes that could affect the quality management system; and
g) recommendations for improvement?

4) Does the output from the management review include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes;
b) improvement of product related to customer requirements; and
c) resource needs?

5) Has the organization determined and provided the resources needed to

a) implement and maintain the QMS?
b) continually improve the effectiveness of the QMS?
c) enhance customer satisfaction by meeting customer requirements?

6. Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed
a) to implement and maintain the quality management system and continually improve its effectiveness, and
b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

The organization shall
a) determine the necessary competence for personnel performing work affecting product quality,
b) provide training or take other actions to satisfy these needs,
c) evaluate the effectiveness of the actions taken,
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

Ensuring the competency of personnel, including newly hired, part-time, and temporary personnel, is essential for the achievement of quality objectives. This pertains to all levels of personnel within the organization that perform activities affecting quality. Ensuring competency includes specific training, as essential for performing assigned tasks, and general training, to build incentives and to heighten quality awareness. Personnel should be trained in the usage of, and the underlying reasons for, the procedures and documents in the organization's quality management system approach.

competence:
demonstrated capability to apply knowledge and skills
[ISO/CD3 19011, 3.14]

☐ Have the persons responsible for providing resources been identified?

To achieve and maintain proficiency, a number of steps can periodically be taken by the organization, as follows

- evaluation of the general education, skills, and experience of the personnel for the activities to be performed;
- identification of individual training needs, as compared to those required for satisfactory performance;
- planning, organizing, and carrying out appropriate activities, either in-house or using an external organization;
- evaluating the effectiveness of the activities;
- recording training and achievement so that records can be updated and gaps can readily be identified and filled (see Clause 4.2.4); and
- evaluating all changes in each process for any additional training requirements.

Training should be given as an introduction for new employees and for all personnel engaged in work affecting quality, and should, as appropriate

- include the intended use of the products;
- identify consequences that could arise from the inadequate or improper performance of the specified tasks; and
- describe any specific requirements for hygiene or other personal attributes.

1) Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills, and experience?

2) Has the organization

   a) determined the necessary competence for personnel performing work affecting quality?
   b) provided training, or taken other actions to satisfy these needs?
   c) evaluated the effectiveness of the training provided or the other actions taken?
   d) ensured that its personnel are aware of the relevance and importance of their activities, and how they contribute to the achievement of the quality objectives?

☐ Have the education, training, skills, and experience requirements been identified?

☐ Do people performing work affecting quality meet the requirements?

☐ Who is responsible for training?

☐ Who is responsible for reviewing training results and determining the effectiveness of training?

☐ Have the requirements for the trainers been identified?

☐ Who is responsible for making people aware of the effect their work has on the achievement of quality?

☐ How and where are the records stored?

e) maintained appropriate records of education, training, skills, and experience?

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable
a) buildings, workspace and associated utilities,
b) process equipment (both hardware and software) and
c) supporting services (such as transport or communication).

6.4 Work Environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

The infrastructure and the work environment are critical elements in obtaining and maintaining proper process control. The definitions provided — in particular the note accompanying the definition of "work environment": "Conditions include physical, social, psychological and environmental factors (such as temperature, recognition schemes, ergonomics and atmospheric composition)" — make it difficult to draw the line between what is considered desirable and what is strictly required by ISO 9001. That is, it may seem difficult to decide which parts of the infrastructure and which aspects of the work environment are "needed to achieve conformity to product requirements". It is of utmost importance that the organization systematically examine its infrastructure and work environment in order to determine exactly what is "needed". The parts of the infrastructure and the aspects of the work environment identified as "needed" will have to be managed, which means that all requirements of the ISO 9001 standard apply to them.

SERVICE

Examples of needed infrastructure and work environment include

infrastructure:
<organization> system of facilities, equipment, and services needed for the operation of an **organization** (3.3.1)
[ISO 9000, 3.3.3]

work environment:
set of conditions under which work is performed
[ISO 9000, 3.3.4]

☐ Who is responsible for the maintenance of buildings, workplace, process equipment, and supporting services?

☐ Does their responsibility cover the need to achieve conformity to product requirements?

a) the biological sterility and uninterrupted power supply in the surgery department of a hospital;
b) soundproofed rooms in the personal services (eg, legal or psychological services); and
c) the effective separation of work areas to avoid cross-contamination in a laboratory doing biological and microbiological work.

☐ Has the work environment been established to achieve product quality?

☐ Is it monitored and maintained?

1) Has the organization determined and managed the work environment needed to achieve conformity to product requirements?

7. Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

In planning product realization, the organization shall determine the following, as appropriate:
a) quality objectives and requirements for the product;
b) the need to establish processes, documents, and provide resources specific to the product;
c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.
NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

Like Clause 5.4.2, which requires the planning of the QMS, Clause 7.1 requires the planning of all the processes related to the realization of the product. The planning of each process may include the following activities (see Figure 10):

a) specifying the inputs required;
b) determining the desired output for the process;
c) establishing the sequence of activities (documented methods as necessary) necessary to obtain the desired output;
d) allocating appropriate resources, in terms of manpower, infrastructure, and work environment; and
e) identifying the necessary measurement and monitoring of the process parameters.

quality plan **document** (3.7.2) specifying which **procedures** (3.4.5) and associated resources shall be applied by whom and when to a specific **project** (3.4.3), **product** (3.4.2), **process** (3.4.1) or contract
[ISO 9000, 3.7.5]

Figure 10
Process Control

ISO 9001:2000 also requires the specification of the required measurement and monitoring of the process output, along with adequate criteria; see the requirements for planning in Clause 8.1. If the required verification of one or more of the output characteristics cannot be made, the process may have to be validated (see Clause 7.5.2).

1) Has the organization planned and developed the processes needed for product realization in a manner that is consistent with the requirements of the other processes of the QMS (see Clause 4.1)?

2) As part of the planning for product realization, has the organization determined the following, as appropriate:
   a) quality objectives and requirements for the product?
   b) the need to establish processes and documents and to provide resources specific to the product?
   c) required verification, validation, monitoring, inspection, and test activities specific to the product, and the criteria for product acceptance?
   d) records needed to provide evidence that the realization processes and resulting product meet requirements?

3) Is the output of this planning in a form that is suitable for the organization's method of operations?

process:
set of interrelated or interacting activities which transforms inputs into outputs
NOTE 1 Inputs to a process are generally outputs of other processes.
NOTE 2 Processes in an **organization** (3.3.1) are generally planned and carried out under controlled conditions to add value.
NOTE 3 A process where **conformity** (3.6.1) of the resulting **product** (3.4.2) cannot be readily or economically verified is frequently referred to a "special process".
[ISO 9000, 3.4.1]

verification:
confirmation, through the provision of **objective evidence** (3.8.1), that specified **requirements** (3.1.2) have been fulfilled
[ISO 9000, 3.8.4]

validation:
confirmation, through the provision of **objective evidence** (3.8.1), that the **requirements** (3.1.2) for a specific intended use or application have been fulfilled
[ISO 9000, 3.8.5]

☐ Who is responsible for establishing the quality objectives, processes, documents, and resources requirements?

☐ Have all the monitoring, measuring, and validation requirements been established and implemented?

☐ Has the need for a quality plan been reviewed and meet?

☐ Have the records generation and storage requirements been determined and implemented?

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine
a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) requirements not stated by the customer but necessary for specified use or known and intended use, where known,
c) statutory and regulatory requirements related to the product, and
d) any additional requirements determined by the organization.

This clause is a key element of ISO 9001:2000. As required by Clause 1.1 a), a QMS is developed and implemented in order to "consistently provide product that meets customer and applicable regulatory requirements". It is therefore critical that the organization clearly define all the requirements related to the product. This clause proposes four sources of requirements:

a) requirements specified by the customer, either verbally or in writing, using any communication medium, such as the phone, the Internet, or a bulky paper-based call for tenders;
b) product characteristics usually not specified by the customer, but related to what is often called the customer's "implied" needs, which are required for the proper customer satisfaction (note: when

requirement:
need or expectation that is stated, generally implied or obligatory
NOTE 1 "Generally implied" means that it is custom or common practice for the **organization** (3.3.1), its **customers** (3.3.5) and other **interested parties** (3.3.7), that the need or expectation under consideration is implied.
NOTE 2 A qualifier can be used to denote a specific type of

determining these requirements, the organization should consider the specified use of the product, as well as other uses known to the organization);

c) product characteristics that are needed to satisfy statutory and regulatory requirements that apply to the product; these include statutory and regulatory requirements from other countries, states, or cities when the product is intended for foreign markets; and

d) other product characteristics that are determined by the organization; these characteristics could be specified to create an image that differentiates a product from similar ones on the market.

requirement, quality management requirement, customer requirement.
NOTE 3 A specified requirement is one which is stated, for example, in a **document** (3.7.2).
NOTE 4 Requirements can be generated by different interested parties.
[ISO 9000, 3.1.2]

SERVICE

In service organizations, the customer may not always specify requirements, and the organization must determine what requirements must be met in order to attract and keep customers. This would be the case for a commercial organization whose customers obtain the service by making their name or a reference number known to the service provider, or by carrying products to the cash register. In such cases, all the requirements for the service and for the delivery processes would come from implied customer needs or expectations, requirements identified by the organization, and regulatory requirements.

1) Has the organization determined

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities?

b) requirements not stated by the customer but necessary for specified use or known and intended use?

c) statutory and regulatory requirements related to the product?

d) any additional requirements?

☐ Who is responsible for determining the customer requirements?

☐ Do product requirements include customer as well as regulatory requirements?

☐ Do we have the current version of the applicable codes and regulations?

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (eg, submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,
b) contract or order requirements differing from those previously expressed are resolved, and
c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

In situations where a tender is offered, a contract is to be established between an organization and a customer, or a customer places an order with an organization, the means of achieving satisfaction lies in the review of requirements.

The review of requirements one of the organization's primary interfaces with its customers. The documented procedures should include a review of customer requirements (whether expressed in a tender, contract, or order, all of which may be written or verbal) and a consideration of how customer requirements are reviewed and communicated within the organization.

The review of requirements takes place prior to accepting a contract or an order.

review:
activity undertaken to determine the suitability, adequacy and **effectiveness** (3.2.14) of the subject matter to achieve established objectives
NOTE Review can also include the determination of **efficiency** (3.2.15).
EXAMPLE Management review, design and development review, review of customer requirements and

Review of requirements is a process that includes the following:

- agreement within the organization that the requirements have been defined, and understood and can be meet, as determined by going through a defined process to verify that the necessary resources and facilities are available;
- resolution of any differences with the customer;
- review of a standard product (eg, "off the shelf" items, a "commodity item", a catalogue item with a published specification, etc), which can be as simple as verifying the accuracy of the information on the order;
- the requirements of a tender, contract, or order, where appropriate, may be translated into the terminology, tolerances, and other necessary information for designing, purchasing, and process control; and
- preliminary quality plan or documented procedures, where appropriate, may be developed, to give an understanding of how to implement the contract successfully and support the review of requirements process.

It is beneficial for the organization to adopt a contract or order review procedure that has the following features:

- affected parties have an opportunity and adequate time to review the contract or order;
- a checklist or some other means (for example, a standard form) is available for reviewers to verify and record that they have reviewed and understood the requirements of the contract or order; and
- a method is available for reviewers to question the requirements of the contract or order, to have their questions considered, and to have differences with other affected parties resolved.

Contracts established to permit supply of product by electronic data interchange (EDI) need especially careful review in order to ensure that the subsequent automatic processes can be operated safely.

1) Has the organization determined and managed the work environment needed to achieve conformity to product requirements?

nonconformity review. [ISO 9000, 3.8.7]

☐ Who ensures that requirements not stated by the customer but necessary to meet statutory and regulatory requirements, and for the safe handling of the product, are established?

☐ How are those methods/requirements reviewed on a regular basis and maintained?

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to
a) product information,
b) enquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints.

The importance of a thorough understanding of the customer's needs, from initial contact, through tendering or receiving verbal orders, to the formulation of the contract or order, as well as in all subsequent stages cannot be overstated. Often, dialogue will be necessary to achieve this understanding, which should clearly establish the customer's requirements as to the product, delivery, and other critical factors. Where a verbal statement of requirement is received from the customer, the organization should ensure that an order (statement of requirements) is understood, adequately documented, and agreed to by the customer.

1) Has the organization reviewed the requirements related to the product?

2) Is this review conducted prior to the organization's commitment to supply a product to the customer (eg, submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders)?

3) Does the review ensure that

   a) product requirements are defined?
   b) contract or order requirements differing from those previously expressed are resolved?
   c) the organization has the ability to meet the defined requirements?

4) Are records of the results of the review and actions arising from the review maintained?

customer:
organization (3.3.1) or person that receives a **product** (3.4.2)
EXAMPLE Consumer, client, end-user, retailer, beneficiary, and purchaser.
NOTE A customer can be internal or external to the organization.
[ISO 9000, 3.3.5]

☐ Who ensures that the customer requirements are appropriate and that the organization is capable of meeting the quality and delivery requirements?

☐ How are customer changes handled?

☐ How are organizational staff made aware of the changes?

☐ Who is responsible for ensuring that order updates are confirmed?

☐ For such things as electronic or catalogue sales, who reviews the catalogue information for accuracy, and who is responsible for

5) Where the customer provides no documented statement of requirements, have the customer's requirements been confirmed by the organization before acceptance?

6) Where product requirements are changed, has the organization ensured that

   a) the relevant documents are amended?
   b) relevant personnel are made aware of the changed requirements?

reviewing this information over a period of time?

☐ Who is responsible for liaising with customers on enquiries, contracts, etc?

☐ Who is responsible for handling customer complaints and customer feedback?

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) the design and development stages,
b) the review, verification and validation that are appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

The essential quality aspects and regulatory requirements such as safety, performance, and dependability of a product are established during the design and development phases.

In considering necessary controls, it is important to note that the design and development process may apply to various activities in different ways and according to different timelines. The organization should consider all phases of its product realization processes.

design and development: set of **processes** (3.4.1) that transforms **requirements** (3.1.2) into specified **characteristics** (3.5.1) or into the **specification** (3.7.3) of

Figure 11 represents a simplified view of the relationship between design and development review, verification, and validation. It has been adapted from *ISO 9000 for Small Businesses — What to do — Advice from ISO/TC 176,* which was prepared by ISO Technical Committee 176 in 1976. These concepts are further explained in Clauses 7.3.2–7.3.7.

a **product** (3.4.2), **process** (3.4.1) or **system** (3.2.1) [ISO 9000, 3.4.4]

quality plan: **document** (3.7.2) specifying which **procedures** (3.4.5) and associated resources shall be applied by whom and when to a specific **project** (3.4.3), **product** (3.4.2), **process** (3.4.1) or contract [ISO 9000, 3.7.5]

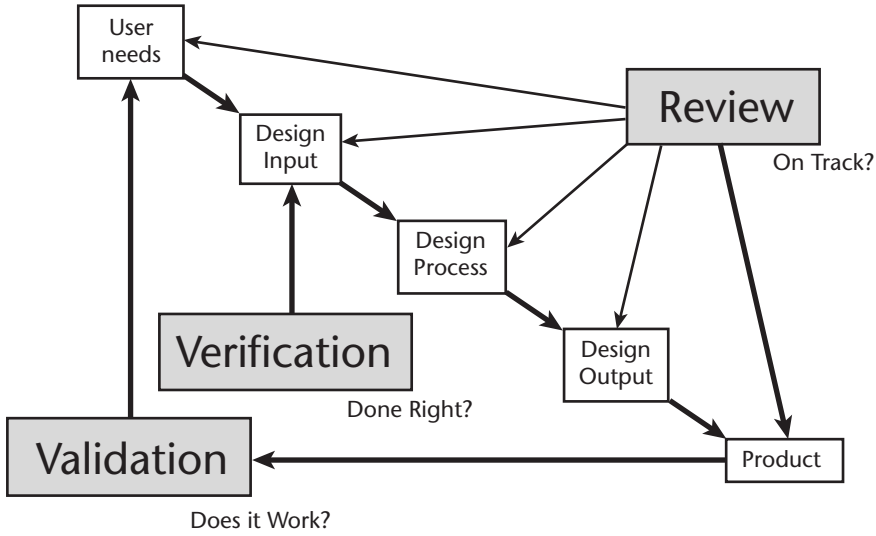


Figure 11
Design and Development Acceptance

During the planning phase, the organization should establish procedures for design and development planning and, where appropriate, include the following:

- identification, scope, and objectives;
- sequential and parallel work schedules;
- timing, frequency, and nature of activities related to design and development verification and to design and development validation;

☐ Have we considered the need to, and utility of, describing our planning output in the format of a quality plan?

- evaluation of the safety, performance, and dependability incorporated in the product design;
- methods of product measurement and test and acceptance criteria; and
- assignment of responsibilities.

Design and development plans should be integrated with any other plans and verification or validation procedures related to the product, and these plans should be updated as necessary. In many instances, the preparation of a quality plan may be of value.

The organization should clearly assign responsibilities for specific leadership and other design and development work functions to qualified personnel. The personnel in these functions should have access to information and the resources needed to complete the work.

Design and development activities should be defined to the level of detail necessary for carrying them out.

When input to design and development is from a variety of sources, the inter-relationships and interfaces, as well as the pertinent responsibilities and authorities, should be defined, documented, coordinated, and controlled.

Many organizational functions, both internal and external, may contribute to the design process. These may include

- research and development;
- marketing and sales;
- purchasing;
- engineering;
- materials technology;
- production/manufacturing;
- service groups;
- facilities management;
- warehousing/transportation/logistics;
- communications;
- information systems;
- regulatory bodies/agencies; and
- subcontractors.

Organizational functions contributing to the design process should also establish, but not limit themselves to, the following:

- the information that should be received and transmitted (in particular, methods should be employed to determine which information is critical to the design and development, so that it can be clearly identified and tracked);
- identification of sending and receiving groups;
- the purpose of the information transmitted;
- identification of transmittal methods; and
- document transmittal and records maintenance.

SERVICE

Clause 7.3 applies to the activities related to the design and development of service delivered to the customer. It is often difficult to separate a delivered service from its delivery process, especially when the customer is present at the interface and the delivery process performance will affect customer satisfaction. Such situations offer a further incentive to make full use of Clause 7.3 to design and develop such realization processes.

Many organizations in the distribution and retail sectors strongly believe that they do not "design products". They are correct in asserting that they do not design the products that they buy and re-sell; however, they do design the service they deliver, as well as the associated processes required to deliver that service. All the subclauses of Clause 7.3 would apply to the design and development of this service, with a level of complexity that is appropriate to the nature of the service delivered.

As well, the service characteristics and the delivery processes are generally modified on a regular basis to follow market evolution. The handling of these modifications should satisfy the requirements of Clause 7.3.7, "Control of design and development changes". A consideration of the definition of "product" will assist in understanding the above (see Appendix B).

1) Has the organization planned and controlled the design and development of product?

2) During the design and development planning, has the organization determined

   a) the design and development stages?
   b) the review, verification, and validation that are appropriate to each design and development stage?
   c) the responsibilities and authorities for design and development?

3) Has the organization managed the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility?

4) Has the planning output been updated, as appropriate, as the design and development progresses?

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These shall include
a) functional and performance requirements,
b) applicable statutory and regulatory requirements,
c) where applicable, information derived from previous similar designs, and
d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

All pertinent design and development inputs (such as performance, functional, descriptive, environmental, safety, and regulatory requirements) should be defined, reviewed for adequacy, and recorded by the organization. These inputs should describe all requirements to the greatest

requirement:
need or expectation that is stated, generally implied or obligatory

possible extent; they lay the foundation and provide a unified approach to the design and development activities. Details agreed upon between the customerand organization on how customer, statutory, and regulatory requirements will be met should be included. Records of the design and development inputs should also include the resolutions of any incomplete, ambiguous, or conflicting requirements that have been identified during design and development control activities.

The design and development inputs should identify design criteria and materials and processes requiring analysis, including prototype testing, to verify their adequacy. These inputs should be prepared in a way that facilitates periodic updates. They should indicate "when" or "what" that criteria will cause the inputs to be updated, specify who is responsible for the update, and stipulate if, and under what circumstances, the customer will get a copy. Inputs prepared in this way contribute a definitive, up-to-date reference document as the design and development activities progress to completion.

Examples of design and development inputs include

- which customer needs and expectations will be included in customer requirements;
- specification for various form of labelling, including service instruction; and
- relevant performance or technical standards and regulations.

1) Has the organization determined the inputs relating to product requirements?

2) Has the organization maintained records of inputs relating to product requirements?

3) Do the inputs determined, and the records maintained include

   a) functional and performance requirements?
   b) applicable statutory and regulatory requirements?
   c) information derived from previous similar designs, where applicable?
   d) other requirements essential for design and development activities?

NOTE 1 "Generally implied" means that it is custom or common practice for the **organization** (3.3.1), its **customers** (3.3.5) and other **interested parties** (3.3.7), that the need or expectation under consideration is implied.
NOTE 2 A qualifier can be used to denote a specific type of requirement, eg, product requirement, quality management requirement, customer requirement.
NOTE 3 A specified requirement is one which is stated, for example, in a **document** (3.7.2).
NOTE 4 Requirements can be generated by different interested parties.
[ISO 9000, 3.1.2]

☐ Do we have the current version of the applicable codes and regulations?

☐ How are design and development documented?

4) Are these inputs reviewed for adequacy?

5) Are the requirements complete, unambiguous, and not in conflict with each other?

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall
a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

Throughout the design and development process, the requirements contained in the design and development inputs description are translated by the organization into outputs. These outputs should be documented in terms that can be verified against the input requirements, using or making reference to acceptance criteria. Examples of design and development outputs include, but are not limited to

- drawings and parts lists;
- specifications (including process and materials specifications);
- actual labelling materials with all instructions;
- software source code;
- servicing procedures;
- procedures for responding to customer complaints; and
- acceptable delivery time for shipping to the customer after receipt of an order.

The design and development outputs are typically the final technical documents used, for example, in purchasing, production, installation, inspection, testing,

characteristic: distinguishing feature
NOTE 1 A characteristic can be inherent or assigned.
NOTE 2 A characteristic can be qualitative or quantitative.
NOTE 3 There are various classes of characteristic, such as the following:
- physical (eg, mechanical, electrical, chemical or biological characteristics);
- sensory (eg, related to smell, touch, taste, sight, hearing);
- behavioral (eg, courtesy, honesty, veracity); - temporal (eg, punctuality, reliability, availability);

or servicing. Because of their impact on follow-on activities, it is important that the each output be reviewed, verified against its corresponding input, and approved before release.

- ergonomic (eg, physiological characteristic, or related to human safety); - functional (eg, maximum speed of an aircraft). [ISO 9000, 3.5.1]

1) Are the outputs of design and development provided in a form that enables verification against the design and development input?
2) Are the outputs of design and development approved prior to release?

3) Do the design and development outputs
   a) meet the input requirements for design and development?
   b) provide appropriate information for purchasing, production, and service provision?
   c) contain or reference product acceptance criteria?
   d) specify the characteristics of the product that are essential for its safe and proper use?

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)
a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

Design and development reviews should be planned. In order to achieve a degree of objectivity, they need to involve all functions, both internal and external, concerned with the design stage that is being reviewed. The timing and frequency of these reviews will be influenced by the maturity, complexity, and cost of the product being

review: activity undertaken to determine the suitability, adequacy and **effectiveness** (3.2.14) of the subject

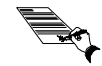
designed. Records of such reviews should be maintained (see Clause 4.2.4).

The competence of the participants in these reviews should be adequate to permit them to examine designs and their implications. The following questions may be considered during these reviews:

a) Do design and development outputs satisfy all specified requirements for the product?
b) Are product design and development characteristics and processing capabilities compatible?
c) Are safety considerations considered?
d) Do design and development outputs meet functional and operational requirements, for example, performance and dependability objectives?
e) Have appropriate materials and/or facilities been selected?
f) Is there adequate compatibility of materials, components, and/or servicing elements?
g) Is the resulting product satisfactory for all anticipated environmental and load conditions?
h) Are components or servicing elements standardized, and do they provide for reliability, availability, and maintainability?
i) Is there a provision in tolerances and/or configuration for interchangeability and replacement?
j) Are plans for implementing the design technically feasible (eg, purchasing, production, installation, inspection, and testing)?
k) Where computer software has been used in design computations, modelling, or analyses, has the software been appropriately verified, validated, authorized, and placed under configuration control?
l) Have the inputs to such software, and the outputs, been appropriately verified and documented?
m) Are the assumptions made during the design process valid?
n) Are the results of model or prototype testing considered?

While the aims of design and development review (Clause 7.3.4), design and development verification (Clause 7.3.5), and design and development validation (Clause 7.3.6) are different, there may be considerable

matter to achieve established objectives
NOTE Review can also include the determination of **efficiency** (3.2.15).
EXAMPLE Management review, design and development review, review of customer requirements and nonconformity review.
[ISO 9000, 3.8.7]



☐ Who is responsible for carrying out a systematic review of the design and development ?

☐ Who is responsible for approving the above **verification** results?

overlap and interrelation between them. This is also illustrated in Figure 11; in many instances, an activity will be relevant to all three requirements (eg, prototype testing and evaluation of test results make a major contribution to all three).

Benefits from the design and development review include

- a systematic assessment of design results;
- feedback to designers;
- assessment of the design project progress; and
- confirmation that the design project is on track and is ready to move to the next stage of development.

In the software industry, the term "development" is generally considered to include "design", as well as requirements analysis, coding, integration, testing, and installation.

During design reviews, aspects inherent to the design activities should be taken into account, such as feasibility, safety, security, programming rules and standards, and testability. The following issues should also be addressed:

- the methods, such as peer reviews, walkthroughs, code inspections, etc, for monitoring the application of rules, practices, and conventions;
- the prerequisites for the conduct of the review, such as establishment of the goals and objectives, meeting delivery commitment, documents required, and roles of review personnel;
- the review techniques to be used and guidelines for participants;
- the success criteria for the review; and
- the follow-up methods to ensure that issues and action items from the review are tracked and resolved.

1) Have systematic reviews of design and development been conducted at suitable stages?

2) Do these reviews

   a) evaluate the ability of the results of design and development to meet requirements?
   b) identify any problems and propose necessary actions?

3) Do the participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed?

4) Are records of the results of the reviews and any necessary actions maintained?

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

Design and development verification is a necessary check to ensure that the design and development outputs conform to specified requirements (design and development inputs). This is an ongoing activity; in some instances, a combination of control measures (eg, design reviews, tests and demonstrations, alternative calculations, comparison with a proven design) may be needed.

The personnel involved in the design and development verification, its timing, and the records to be retained should all be considered in the design and development planning phase (Clause 7.3.1).

When alternative calculations or comparison with a proven design are employed as forms of design and development verification, the appropriateness of the alternative calculation method and/or proven design should be evaluated in relation to this new application.

verification: confirmation, through the provision of **objective evidence** (3.8.1), that specified **requirements** (3.1.2) have been fulfilled [ISO 9000, 3.8.4]

objective evidence: data supporting the existence or verity of something
NOTE Objective evidence may be obtained through observation, measurement, **test** (3.8.3), or other means. [ISO 9000, 3.8.1]

When tests and demonstrations are employed as a form of design and development verification, the safety and performance of the product should be verified under conditions that are representative of the full range of circumstances of actual use. The product units employed for tests and demonstrations should be produced under the expected production conditions.

☐ Who is responsible for verifying design and development outputs against their corresponding input requirements?

SERVICE

The design and development verification in the case of a training course, for example, is the determination that the course content and the course material meet all the requirements identified in their corresponding design and development inputs, and that they cover all the expected subject matter.

1) Has verification been performed to ensure that the design and development outputs have met the design and development input requirements?

2) Have records of the results of the verification and any necessary actions been maintained?

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

Design and development validation is necessary to confirm that the end product fulfills the specified requirements for its intended use. It may be necessary to involve the customer in design validation.

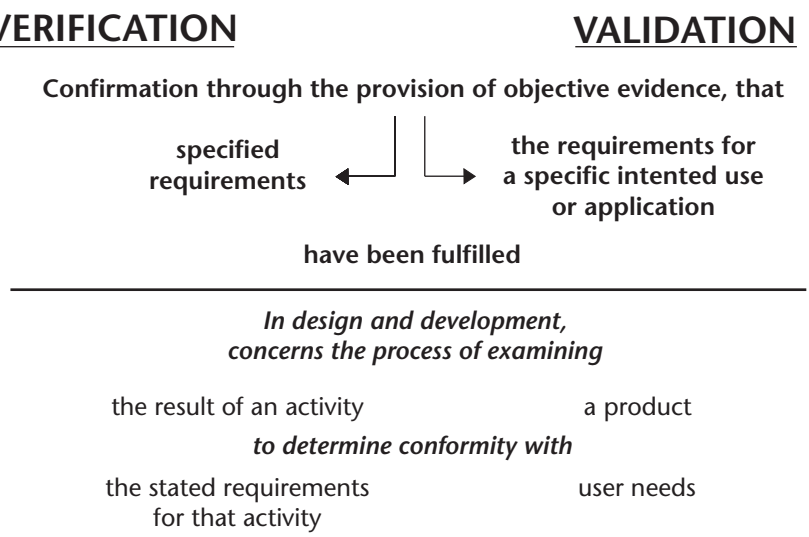


Figure 12
Verification and Validation

Figure 12 illustrates the association, as well as the important differences, between the concepts of design and development verification and design and development validation.

After successful design and development verification, a design and development validation should be performed under defined conditions for the use of the final product. However, validation may be necessary at earlier stages, if there are features that it is not possible or practical to validate at the final stage. Conversely, there will be situations in which validation can only be performed by observation during the initial use of the product.

Design and development validation goes beyond the purely technical issues of verifying that the design and development outputs meets their corresponding inputs (which is design and development verification; see Clause 7.3.5); it is intended to ensure that the product meets user requirements. This involves consideration of the knowledge and capabilities of the intended user, the operating instructions, compatibilities with other systems, and any restriction on the use of the product.

validation:
confirmation, through the provision of **objective evidence** (3.8.1), that the **requirements** (3.1.2) for a specific intended use or application have been fulfilled
[ISO 9000, 3.8.5]

☐ Have we recorded results of our design and development **validation?**

The product units employed for validation should be produced under the conditions specified as "final", "normal", or "commercial" for the product, eg, initial production units. The design and development validation should be conducted under actual or simulated use conditions.

SERVICE

An example of design and development validation for services is the validation training session delivered by a training organization to a representative sample of the targeted audience, prior to publicly offering the training session. The evaluation that follows such validation session often reveals where fine-tuning is needed for the course content, material, environment, etc.

1) Has design and development validation been performed in accordance with planned arrangements (see Clause 7.3.1)?

2) Does the validation ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known?

3) Where practical, has the validation been completed prior to the delivery or implementation of the product?

4) Have records of the results of validation and any necessary actions been maintained?

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

A product may be changed or modified for a number of reasons, for example

- omissions or errors (eg, in calculation, material selection, etc) during a phase in the design and development process that have been identified afterwards;
- manufacturing, installation, or servicing difficulties found after the design and development phase;
- the customer or subcontractor requests changes
- a characteristic or performance feature of a product is to be improved;
- changes required by safety, regulatory, or other requirements;
- the result of design and development review (see Clause 7.3.4), design and development verification (see Clause 7.3.5), or design and development validation (see Clause 7.3.6) requires change; and
- corrective or preventive action requires change (see Clauses 8.5.2 and 8.5.3).

review:
activity undertaken to determine the suitability, adequacy and **effectiveness** (3.2.14) of the subject matter to achieve established objectives
NOTE Review can also include the determination of **efficiency** (3.2.15).
EXAMPLE
Management review, design and development review, review of customer requirements, and nonconformity review.
[ISO 9000, 3.8.7]

Any changes to design and development inputs should be identified and reviewed by the organization to determine whether they influence the previously approved review, verification, or validation results. Design and development changes in one component of a product should be evaluated for their influence on the whole. Improving one characteristic may have unforeseen adverse influence on another.

When significant changes are made, the design and development verification and validation procedures should also be reviewed and modified as appropriate.

Procedures should be established to communicate the new design and development output to all concerned, to record any changes, and to ensure, as well as record, that all authorized design changes, and only those changes, are implemented.

When a product that has already been placed on the market is changed, the organization should consider the following questions, among others, before permitting the change to an approved design:

a) Will the product still conform to the product specifications?
b) Will the intended use be affected?
c) Will different components of the product or system be affected by the change?
d) Will the change create problems in manufacture, installation or use?
e) Will the change affect the regulatory status of the product?

Design and Development Transfer

The transfer of a design to production normally follows successful design and development reviews, verifications, and validation.

It may not be possible to determine the adequacy of full-scale manufacturing (or in the case of the service industry, delivery of a service to customer) on the basis of successfully building prototypes or models in a laboratory and testing these prototypes or models. The engineering feasibility and production feasibility may be different because the equipment, tools, personnel, operating procedures, work environment, supervision, and motivation may be different when a company scales up for routine production. One way to ensure that distributed product has the quality attributes established during the design phase, and to ensure that these attributes are not adversely affected by the full-scale production process, is to make and deliver finished product using the approved specifications, the same materials and components, the same production and assessment equipment, and the same methods and procedures that will be used for routine production.

Where appropriate, this may be accomplished by making "pilot runs" or "first production runs".

SERVICE

As already discussed under Clause 7.3, with reference to the applicability of design and development requirements to service, the requirements of Clause 7.3.7 apply in many instances. For example, service characteristics the delivery processes are generally modified on a regular basis, to follow the evolution of

the markets. These modifications are subject to the requirements of Clause 7.3.7.

In software development, the control of changes is usually addressed under the discipline of configuration management (see ISO 10007:1995). Changes to a software product should be planned so as to maintain consistency between requirements specifications, design specifications, code, test specifications, and user manuals.

The organization should control the implementation of any design changes that may arise at any time during the product life cycle, in order to

- document and justify each proposed change;
- evaluate the consequences of each change;
- approve or disapprove all changes;
- notify all affected parties of approved changes;
- plan and implement all approved changes; and
- verify and validate all implemented changes.

1) Have design and development changes been identified and records maintained?

2) Have the changes been reviewed, verified, and validated as appropriate, and approved before implementation?

3) Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and already delivered product?

4) Have records of the results of the review of changes and any necessary actions been maintained?

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

To ensure that purchased products that become part of, or affect the quality of, the organization's product conform to specified requirements, purchasing should be planned and carried out under adequate control by the organization. Planning and controls should include, but not be limited to, the following:

- evaluation and selection of suppliers;
- development of clear and unambiguous purchasing requirements (see Clause 7.4.2); and
- performance of suitable verification and implementation of receiving inspection procedures (see Clause 7.4.3).

The organization should establish an effective working relationship with its suppliers and put a feedback system in place.

Clause 7.4 is not limited to products incorporated into the final product, or to products that come in contact with the final product. It applies to any product that may have an effect "on subsequent product realization or the final product". Examples of purchased products or services include

- raw materials, components, or subassemblies;

supplier:
organization (3.3.1) or person that provides a **product** (3.4.2)
EXAMPLE Producer, distributor, retailer or vendor of a product, or provider of a service or information.
NOTE 1 A supplier can be internal or external to the organization.
NOTE 2 In a contractual situation a supplier is sometimes called "contractor".
[ISO 9000, 3.3.6]

requirement:
need or expectation that is stated, generally implied or obligatory
NOTE 1 "Generally implied" means that it is custom or common practice for the **organization** (3.3.1), its **customers** (3.3.5), and other **interested parties** (3.3.7), that the

- completed product bearing the mark and/or name of the organization; the product may be ready for sale or may still require further processing, such as packaging and/or sterilization;
- services such as machining, heat treating, calibration, testing, pest control, waste disposal, cleaning, environmental monitoring, laundry, transport, and installation;
- specialist professional advice/consulting services; and
- products related to the maintenance of the infrastructure, where poor quality may have an impact on, for example, specified delivery dates.

expectation under consideration is implied.
NOTE 2 A qualifier can be used to denote a specific type of requirement, eg, product requirement, quality management requirement, customer requirement.
NOTE 3 A specified requirement is one which is stated, for example, in a **document** (3.7.2).
NOTE 4 Requirements can be generated by different interested parties.
[ISO 9000, 3.1.2]

In developing methods to ensure the conformity of purchased product, the organization is required to establish that all suppliers have the capability of supplying products that meet the specified requirements.

The organization should evaluate the capabilities of suppliers. The extent of evaluation varies according to the importance of the purchased product and its impact on the final product.

Such an evaluation, then, might involve a comprehensive audit of the supplier's QMS, or simply accepting an evaluation and approval by reference to historical data, eg, records of past performance, certified products, or QMS registration schemes. In any event, the organization is required to be able to demonstrate that formal consideration was given to the evaluation and that the selection of suppliers was based on an approval appropriate to the product being purchased.

The organization should be able to demonstrate that suppliers are evaluated on the basis of performance. Records of the evaluation and subsequent actions must be maintained (see Clause 4.2.4).

The extent to which the supplier may change its manufacturing process (including subcontracting some of the work) without formal approval by the organization may need to be defined in the contract. Changes by the supplier in its manufacturing process that could affect

quality should be reviewed and, after approval by the organization, correctly implemented.

1) Has the organization ensured that purchased product conforms to specified requirements?

2) Is the type and extent of control applied to the supplier dependent upon the effect of the purchased product on subsequent product realization or the final product?

3) Has the organization evaluated and selected suppliers based on their ability to supply product in accordance with the organization's requirements?

4) Has the organization established the criteria for selection, evaluation, and re-evaluation of suppliers?

5) Have records of evaluations of suppliers and any necessary actions arising from the evaluations been maintained?

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

To ensure the quality of the finished product, the organization's purchasing data should define the specified requirements to the supplier including technical product requirements, calibration or other services, special processes, and inspection and test activities. Such requirements may be specified, in part, by reference to

other applicable technical information, such as national or international standards, test methods, etc. Another approach is to clearly and precisely state the information on the purchase order. Responsibilities for reviewing and approving the purchasing data should be clearly assigned to appropriate personnel.

Clarity in the specification documents and an agreement on the part of the supplier to provide the product or service in accordance with the specifications are essential ingredients of successful outsourcing. The contract should also include an agreement between the parties as to what methods of assuring quality will be used to decide the acceptability of product or service.

1) Does the purchasing information describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment?
b) requirements for qualification of personnel?
c) QMS requirements?

2) Has the organization ensured the adequacy of specified purchase requirements prior to their communication to the supplier?

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

Receiving inspection is one method for the organization to verify that purchased items delivered to the organization's facilities meet specified requirements for quality.

inspection:
conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging
[ISO 9000, 3.8.2]

The organization's procedures or quality plan should specify the method of verifying that shipments received are in accordance with specifications, are complete, have proper identification, and are undamaged. The procedures should also include provisions for verifying that incoming items, materials, or services are accompanied by the required supporting documentation (eg, certificates of conformity, mill test reports, and acceptance test reports). Appropriate action in the event of nonconformities should be specified (see Clause 4.13). Analysis of past receiving inspection data, in-plant rejection history, or customer complaints should influence the organization's decisions regarding how much inspection is required and whether a subcontractor should be reassessed.

When contractually specified, the organization may be involved with verification activities at the supplier's premises.

Where this is the case, the organization should include special clauses or statements in purchasing documents regarding verification procedures and product release methods (eg, product shipment should have prior approval of the organization).

When specified by the customer, the organization should include special clauses or statements in subcontracts when verification is required at source (eg, the supplier's facilities).

When specified in the contract between the organization and a customer, the latter may extend verification activities to the facilities of the organization, to assure that the product meets the specified requirements. In such cases, the organization should arrange for the customer to verify the quality of the supplier's product and, if necessary, the effectiveness of the process.

Release of incoming product subject to recall should be discouraged as a matter of good quality management practice. Product should only be released, subject to recall, if

- an objective evaluation of quality status and solution of any nonconformities can still be implemented; and
- correction of nonconformities cannot compromise the quality of adjacent, attached, or incorporated product.

The organization's procedures should define who is authorized to allow incoming product to be used without prior demonstration of conformity to specified requirements for quality. The organization's procedures should also define how such product will be positively identified and controlled in the event that subsequent inspection finds nonconformities.

Where the contract provides, the customer may use the organization's data to decide which of the products to be purchased will require verification at source and to decide the nature and extent of such verification.

If the customer, on verification of the supplier's product, expresses satisfaction, the organization should not take this as an opportunity to relax controls. The organization retains full responsibility for the quality of the product being supplied to the customer.

1) Has the organization established and implemented the inspection or other activities necessary for ensuring that purchased product meets specified requirements?

2) Where the organization or its customer intends to perform verification at the supplier's premises, has the organization stated the intended verification arrangements and method of product release in the purchasing information?

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,
b) the availability of work instructions, as necessary,
c) the use of suitable equipment,
d) the availability and use of monitoring and measuring devices,
e) the implementation of monitoring and measurement, and
f) the implementation of release, delivery and post-delivery activities.

The organization's planning for the production, installation, and servicing processes should consider each of the controlled conditions described in Clause 7.5.1. Control within the process, to prevent nonconformities from occurring, is preferable to inspection of the finished product or the servicing alone. When appropriate, the characteristics that are most critical to the product quality should be identified and subjected to process control procedures.

Process control activities may include procedures for accepting materials or items into the process and determining their characteristics while in-process. The amount of in-process testing and inspection performed will depend partly on the effect of nonconformities on the following processes. The adequacy of measurement processes should be considered in reviewing the effectiveness of production process control.

The organization should include within the scope of the QMS the proper maintenance of process equipment and essential materials. It is the organization's responsibility to establish process capability and define the maintenance activities that will ensure continuing process capability. Figure 10 illustrates an approach to controlling the results expected from any process; it is applicable to all processes of the QMS (Clauses 4, 5, 6, 7, and 8), not just those specified in Clause 7.

☐ Are the key processes that directly affect quality identified?

☐ Who is responsible for process procedure development, change, and issue?

☐ How are the processes controlled?

☐ Who is responsible for process monitoring and the recording of results?

☐ Who determines the qualifications necessary for process operators?

Figure 10 illustrates the process control approach, in which human resources, work environment, infrastructure, planning methods, and monitoring and measuring processes are identified as areas that may need control and that may have a major impact on results expected from a given process. Also highlighted in Figure 10 is the fact that actual outputs require verification, inspection, and testing based on internal references or external metrological standards. This requirement is explored in greater detail under Clauses 7.6 and 8.4.2, later in this handbook.

In software development, provisions for the control of the processes for production apply to the replication, delivery, and installation of software products.

To ensure that the replication process is adequately controlled, the following should be considered:

- identification of the master and the copies, including type of media and format, variant, version, and associated labelling;
- checks against the possibility of software viruses;
- controlling the equipment and environment under which replication is performed, to ensure repeatability; and
- verification of the accuracy and completeness of the copies.

Delivery of a software product may be a series of staged or phased releases, with only the final delivery providing the full set of contractual requirements. In such cases, the organization should document the requirements that are fulfilled in each phased release, as well as operational restrictions, if applicable. Such information should be conveyed to the customer prior to delivery.

Software products may be delivered by the physical transfer of media containing software or by electronic transmission. Where electronic transmission is used, consideration should be given to

- methods for ensuring the integrity of the transmitted software, such as error detection and correction techniques;

- methods for providing security and protecting the confidentiality of transmitted software and data, such as password-enabled access and data encryption; and
- protection against damage by software viruses.

When installation of the software product is contractually required, the organization and the customer should agree on their respective roles, responsibilities, and obligations, and such agreements should be documented.

When service is provided, as in the case of a software service bureau, the following should be addressed:

- documentation of details of changes, including both functional and operational differences, since the previous release;
- the process for notifying customers of new releases and all associated changes;
- methods for providing security and protecting the confidentiality of customer data and information (see ISO 9001:2000, Clause 7.5.4);
- development of a migration or transition plan for each new release;
- planning for service support, such as the provision of a help desk for users, and methods for handling customer complaints; and
- methods for archiving, backup, and recovery, including contingency planning.

1) Does the organization plan and carry out the production and service provision under controlled conditions?

2) Do the controlled conditions include, as applicable

   a) the availability of information that describes the characteristics of the product?
   b) the availability of work instructions, as necessary?
   c) the use of suitable equipment?
   d) the availability and use of monitoring and measuring devices?
   e) the implementation of monitoring and measurement?
   f) the implementation of release, delivery, and post-delivery activities?

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable
a) defined criteria for review and approval of the processes,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records (see 4.2.4), and
e) revalidation.

Some processes are such that the product quality characteristics cannot be fully verified after the completion of the processes. Although these processes are found in all generic product categories — hardware, software, processed materials, and services — they are particularly common in the production of processed materials and services. Examples include circumstances where

- certain product characteristics do not exist until later in the process or until the product (service) is delivered;
- the method of measurement does not exist or is destructive to the product; and
- it is not possible or practical to measure a characteristic in later inspections or tests.

Cases in which critical product quality characteristics fall within one or more of the three process circumstances above include

- strength, ductility, fatigue life, and corrosion resistance of a metal part following welding, soldering, heat treatment, or plating;
- shrinkage and tensile properties of a polymerized plastic;

validation: confirmation, through the provision of **objective evidence** (3.8.1), that the **requirements** (3.1.2) for a specific intended use or application have been fulfilled [ISO 9000, 3.8.5]

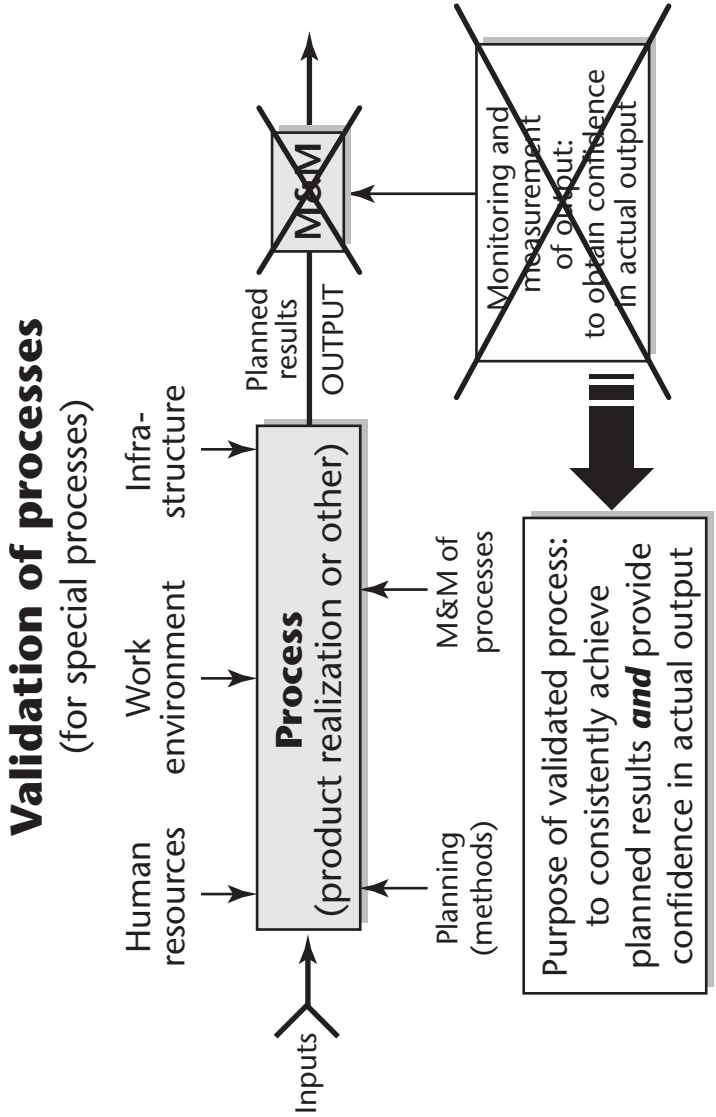


Figure 13
Validation of Processes

- taste, texture, and appearance of a bakery product; and
- correctness of a software product or a financial or legal document.

Such products are typically the final result of a series of operations, and their production requires close adherence to specified in-process procedures and sequences, such as the following:

- for a hardware or processed materials product, starting materials, temperature profiles, physical deformations, mixing, and environmental conditions; and
- for a software or service product, source data and documents that are subject to regulatory and copyright requirements.

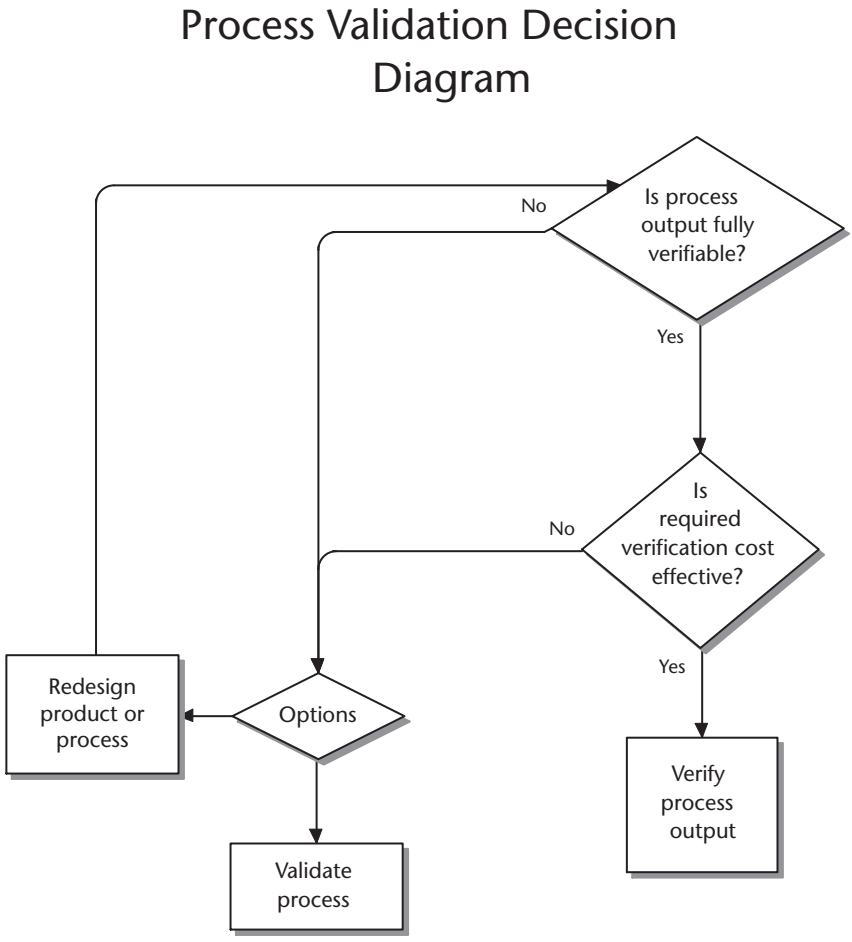
Such processes should require comprehensive measurement assurance and calibration of equipment used to produce or measure the product. Where suitable, process control should include statistical process control methods, supplemented by procedures to maintain the suitability of software, of in-process materials, and of activities needed for appropriate storage, handling, and segregation.

The qualification requirements (eg, skills, knowledge, and physical capabilities) of personnel should be stated, and conformity to the requirements should be demonstrated.

Process knowledge can be used to differentiate finished product characteristics from measurable in-process characteristics. Such processes should have stated qualification requirements and should be qualified, in advance, by examination, inspection, measurement, or test, so as to verify that the process can meet the specified requirements. Records of these requirements should be maintained (see Clause 4.2.4).

Processes must usually be validated because their outputs cannot be verified. However, processes may be validated for other reasons. For example, the verifications required for the output of a process might

not be cost- effective, and might be replaced with a combination of process validation and sample verification. Figure 14 shows a process validation decision tree.



Provided by Accademia Qualitas and Health Canada

Figure 14
Process Validation Decision Tree

SERVICE

Service delivery processes that involve direct contact with the customers should be validated. Although the process outputs can often be verified by monitoring or measurement, the deficiencies become apparent during the contact with the customer. The most effective way to satisfy the customers is to fully validate the processes.

For any applications software or software-based equipment used in processes for production and service provision, the applicability of the software to those processes should be considered in the course of validating and approving such software/equipment. In addition, training in the use of the software should be considered as part of the qualification requirements for operating personnel (see Clause 6.2.2).

1) Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement?

2) Does the organization validate any processes where deficiencies become apparent only after the product is in use or the service has been delivered?

3) Does this validation demonstrate the ability of these processes to achieve planned results?

4) Has the organization established arrangements for these processes including, as applicable

   a) defined criteria for review and approval of the processes?
   b) approval of equipment and qualification of personnel?
   c) use of specific methods and procedures?
   d) requirements for records (see Clause 4.2.4)?
   e) revalidation?

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

Where appropriate, the organization should define the means for product identification; this may be done by marking or tagging or by specifying the location of the product or its container. For example, on visually identical parts having different functional characteristics, different colours can be used. For bulk products or product from continuous processes, the identification may be provided by marking batches or well-defined lots and supplying accompanying documents. Service identification may be achieved by documentation that accompanies the service or by recording the stage of the service delivery as it progresses.

Product traceability consists in the ability to trace the history, application, or location of an item or activity by means of recorded identification. Traceability is typically required when there is a need to track a nonconformity back to its source and to determine the location of the remainder of the affected batch. Traceability may entail additional cost and, when it is specified in the contract, the extent of quality records should be stated.

The organization can achieve traceability by providing each individual product with an identifier (eg, serial number, date code, batch code, lot number) unique to the source of operation. Separate identifiers could be required for changes in operative personnel, changes in raw materials, changes in tooling, new or different

traceability: ability to trace the history, application or location of that which is under consideration
NOTE 1 When considering **product** (3.4.2), traceability can relate to
- the origin of materials and parts;
- the processing history, and
- the distribution and location of the product after delivery.
NOTE 2 In the field of metrology the definition of VIM:1993, 6.10, is the accepted definition.
[ISO 9000, 3.5.4]

☐ How are personnel involved in the service delivery process identified?

☐ Who is responsible for product identification from receipt to use?

machine setups, changes in process methods, etc. Traceability identifiers should appear on applicable inspection and stock records (see Clause 4.2.4).

SERVICE

In some situations, traceability requires identification of the specific personnel involved in each phase of product processing or delivery. A sequence of individuals may perform successive service functions, each of whom must be traceable. The recording of identification evidence through signatures on serially numbered documents in invoicing and banking operations are examples. Here there is no tangible product as such, but each individual's identification evidence should be traceable.

The identification on products enables traceability in two directions: forward, to customers; and backward, to raw materials, personnel, components, and processes used in manufacture.

The extent to which raw material and components need to be identified and related to finished product batch, lot, or serial number depends upon such factors as

- the material involved;
- the type of finished product;
- the effect of failure of finished product or material used therein;
- specified requirements;
- design output; and
- regulatory requirements.

In software development, configuration management is a means by which identification and traceability may be achieved (see ISO 10007:1995). Use of configuration management depends on the project size, complexity of the product, and the risk level. A configuration management system should provide the capability to

- uniquely identify the versions of each software item;
- identify the versions of each software item that together constitute a specific version of a complete product;

☐ How is the identification achieved and maintained?

☐ Is traceability a specified requirement?

If so:
☐ Who is responsible for maintaining traceability?

☐ What determines a batch lot?

☐ How is a batch lot identified?

☐ How is this recorded?

- identify the build status of software products under development, delivered, or installed;
- control simultaneous updating of a given software item by two or more people working independently;
- provide coordination for the updating of multiple products in one or more locations, as required; and
- identify and track all actions and changes resulting from a problem report or change request, from initiation through to release.

1) Where appropriate, has the organization identified the product by suitable means throughout product realization?

2) Has the organization identified the product status with respect to monitoring and measurement requirements?

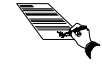
3) Where traceability is a requirement, has the organization controlled and recorded the unique identification of the product?

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

The organization, upon receipt of customer-supplied product that is furnished to the organization for use in meeting the requirements of the contract, accepts responsibilities for prevention from damage and for identification, preservation, storage, handling, and use while that product is in the organization's possession.



☐ Does this clause of ISO 9001:2000 apply to my organization?

If yes:
☐ Who is responsible for control of

The organization should therefore establish arrangements, as necessary, for the following:

- examination of the product upon receipt, to check the quantity received and its identity, and to detect any damage in transit;
- periodic inspection during storage, to detect any signs of deterioration, to check the limitations on time in storage, to assure maintenance of proper conditions, and to determine the current state of the product;
- compliance with any contractual requirements; and
- identification and safeguarding of the supplied product, to prevent any unauthorized use or improper disposal.

The responsibility should be defined for reporting unsuitability to the customer, who is responsible for providing acceptable product within the terms of the contract. Records of products that are lost, damaged, or otherwise unsuitable for use should be maintained (see Clause 4.2.4).

Although the organization is responsible for routine maintenance of customer-supplied product, any maintenance that requires detailed knowledge of the product may, for example, be covered by a maintenance contract between the customer and a third party. The arrangement and responsibility for third-party maintenance of customer-supplied product should be stated in the contract.

The organization should consider the significance of customer-supplied product during contract review, particularly when the customer-supplied product is a service — for example, the use of a customer's transport for delivery. The organization should be able to show documentary evidence that this is being done, where appropriate. The organization should obtain from the customer, as appropriate, information or requirements concerning handling, storage, and maintenance of customer-supplied product.

When necessary, the need for calibration of customer-supplied tools and equipment should be specified by the customer.

supplied product?

☐ Does the scope of the procedure cover all customer-supplied material, components, etc?

☐ How are deficiencies in the customer-supplied product or service recorded?

☐ Who contacts the customer if problems occur with its product?

☐ Have material control procedures been referenced?

SERVICE

The term "customer property" is easily visualized when material is handed by the customer to the organization for incorporation into the final product, or for handling through the service delivery process. All customer property must be covered, including those that are often overlooked, such as

- services provided by the customer, such as transportation and testing services;
- equipment provided by the customer to verify the conformity of service at the organization's facilities;
- computer software used when outsourcing services;
- proprietary material or information provided to deliver the service;
- information provided by the customer that is necessary to perform a service, for example, in the provision of legal, medical, and hospitality services; and
- infrastructures and working environment, when an organization has to perform a service on the customer premises.

1) Does the organization exercise care with customer property while it is under the organization's control or being used by the organization?

2) Does the organization identify, verify, protect, and safeguard customer property provided for use or incorporation into the product?

3) If any customer property is lost, damaged, or otherwise found to be unsuitable for use, is this reported to the customer, and records maintained?

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

The organization's QMS should provide adequate planning, control, and documentation for handling, storage, packaging, preservation, and delivery of product. This applies to in-process materials and finished product.

The organization's method for handling product should consider providing equipment such as antistatic wrist straps, gloves, and protective clothing, as well as transportation units, such as pallets, containers, conveyors, vessels, tanks, pipelines, or vehicles. This is necessary so that damage, deterioration, or contamination (due to vibration, shock, abrasion, corrosion, temperature variation, electrostatic discharge, radiation, or any other conditions occurring during handling and storage), may be prevented. Maintenance of handling equipment is another factor to be considered.

The organization should provide suitable storage facilities, considering not only physical security but also environmental conditions (eg, temperature and humidity). It may be appropriate to check items in storage periodically to detect possible deterioration. The methods for identification should give legible, durable information, in accordance with the specified requirements. Consideration may need to be given to administrative procedures for product expiration dates, stock rotation, and lot segregation.

Orderly storage conditions enable rapid and accurate identification of stock and facilitate cleaning, while minimizing risk of damage.

During storage and transportation up to the point of use, the packaging of the product is intended to provide

☐ Who is responsible for the overall material-handling function?

☐ Who specifies methods of handling, storage, packaging, preservation, and delivery?

☐ Who audits this activity?

☐ What handling methods are necessary to prevent damage or deterioration?

☐ Are in-process handling methods defined?

☐ What areas are designated for storage?

☐ Who authorizes receipt and dispatch from storage areas?

☐ At what interval is the condition of product in stock assessed?

☐ How are the assessments recorded?

☐ Who identifies the cartons and/or containers?

appropriate protection against damage, deterioration, or contamination of the product.

Before any packaging of the product is adopted, the appropriateness of the packaging for its intended use should be validated. For example, the effectiveness of the packaging may be demonstrated by journey hazard trials designed to simulate the abuses that the package will encounter during storage and transportation.

SERVICE

This clause also applies to the preservation of confidential information and other intellectual property during the "handling", "packaging", and "transportation" of information and data, ensuring the these activities do not change the contents.

1) Does the organization preserve the conformity of product during internal processing and delivery to the intended destination?

2) Does this preservation include identification, handling, packaging, storage, and protection?

3) Does this preservation also apply to the constituent parts of a product?

☐ What packing, packaging, and marking are necessary?

☐ How is the packaging evaluated for effectiveness?

☐ What preservation methods are necessary for the product?

☐ How is product segregated?

☐ How is the quality of the product protected during the delivery phase?

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall
a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
b) be adjusted or re-adjusted as necessary;
c) be identified to enable the calibration status to be determined;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

This clause applies to monitoring and measuring devices used to demonstrate conformity of the product to specified requirements.

measuring equipment: measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof

Although the requirements pertain explicitly to monitoring and measuring devices, including test software, it is helpful to approach the subject from the

perspective that measuring is itself a process involving materials, equipment, and procedures. The requirements explicitly involve elements of the measurement process — elements whose collective purpose is to choose suitable measurements, suitable inspection, measuring, and test devices, and suitable measurement procedures. These elements are specified to give the organization and its customers confidence that the organization's measuring systems can adequately control the production and inspection of the product.

Statistical methods are valuable tools for achieving and demonstrating fulfillment of requirements. Statistical methods are particularly important in showing that monitoring and measuring devices are used in a manner that ensures measurement uncertainty is known and is consistent with the required measurement capability.

All test equipment must be calibrated. In addition, where it is necessary to have recording or controlling instruments on manufacturing equipment, these instruments should be calibrated initially and at defined intervals in accordance with a planned schedule.

The limits of accuracy of the calibration should meet or exceed the limits of accuracy of the test for which the calibrated equipment is being used.

Monitoring and measuring devices are not always used for purposes that affect the quality of the product or service provided by the organization. As a result, some devices may not need to be part of the organization's control program. For example

- instruments used to provide only an indication, eg, a pressure gauge that is used only to determine the existence of line pressure, not to control the actual manufacturing process;
- instruments that are associated with business administration, eg, clocks used to control working times or thermostats used to control operator comfort; and
- instruments that may be installed on process equipment, but are not used for process control.

necessary to realize a **measurement process** (3.10.2)
[ISO 9000, 3.10.4]

measurement process: set of operations to determine the value of a quantity
[ISO 9000, 3.10.2]

configuration management: technical and organizational activities comprising:
configuration identification;
configuration control;
configuration status accounting;
configuration auditing.
[ISO 10007:95, 3.9]

configuration identification: activities comprising determination of the product structure, selection of configuration items, documenting the configuration item's physical and functional characteristics including interfaces and subsequent changes, and allocating identification characters or numbers to the configuration items and their documents.
[ISO 10007:95, 3.7]

configuration item: aggregation of hardware, software, processed materials, services, or any of its discrete portions, that is designed for configuration management and treated as a single

If the organization decides to perform its own calibration, procedures must be established for calibrating each type of equipment used. If the calibration work is subcontracted, the requirements identified in Clause 7.4 must be addressed, along with, some additional issues:

- ideally, the subcontractor should be a certified calibration service; and
- the subcontractor should issue a certificate of calibration, which states the uncertainty of measurement, and indicates traceability back to a national or international standard.

If equipment is found to be faulty, it is important to determine at what stage the error first occurred. Then it is necessary to decide what action must be taken about product that has passed any tests using that faulty equipment. Options range from the decision that no action is required to the judgment that a product recall is necessary.

Unlike hardware test equipment, test software does not experience "drift" or ageing, so periodic verification may not appear to be necessary. However, software can be subject to unintended change; the purpose of periodically verifying test software is to ensure its continuing capability to perform the required measurements.

Some form of secure write protection should be used with test software, in the same manner as seals are used on hardware calibration adjustments, to minimize the possibility of inadvertent changes.

The word "equipment" in the fourth paragraph of Clause 7.6 should be interpreted as meaning "measuring equipment".

SERVICE

In the case of service, the measuring of processes or of their results is not necessarily done, in a traditional sense. Measuring equipment or devices in this case may take the form of such tools as surveys of customer satisfaction or questionnaires completed after the service is delivered to customers, the marketplace, or

entity in the configuration management process. [ISO 10007:95, 3.8]

☐ What is the scope of the equipment covered?

☐ Who is responsible for control, calibration, and maintenance of inspection, measuring, and test equipment?

☐ What means are used to ensure that equipment is used properly and for its intended purpose?

☐ How are software or comparative references checked, and at what frequency?

☐ How and when is technical data pertaining to measurement devices made available to the customer?

☐ What measurements are to be made and at what accuracy?

☐ What is the method for equipment selection?

☐ How is the equipment identified?

☐ What is the calibration process?

☐ What is the basis for calibration?

☐ How is the calibration status indicated?

other interested parties. Such questionnaires could seek to determine whether a service meets customer requirements. From the perspective of conformity assessment, the survey data should facilitate the determination of whether the delivered service met the "service requirements". The application of statistical techniques is often part of these tools, especially when the organization wants to extrapolate the results to make generalizations about the overall service delivered by the organization. The organization must then ensure that the measurement was done on a representative sample.

☐ What documents become quality records?

☐ When equipment is found to be out of calibration, how is the validity of previous results assessed?

☐ How is equipment safeguarded?

When the organization uses software or firmware-based monitoring or measuring devices to conduct inspections or tests that verify or validate the conformance of a deliverable product to specified requirements, the organization should ensure that the software or firmware is capable of verifying the acceptability of the deliverable product. Such confirmation of the software or firmware's monitoring or measuring capability should be made prior to its use, and re-confirmed at periodic intervals, as appropriate. The time interval of re-confirmation should be determined in accordance with such factors as the retention period of the recording media and exposure to such conditions as electromagnetic interference or computer viruses, which are likely to introduce errors.

Prior to use, the software or firmware used in monitoring or measuring devices should be placed under configuration management control. As the software or firmware may require improvements or upgrades to reflect changing product requirements or revisions to the product, the means to readily associate a given version of software or firmware with a given revision of the deliverable product should be considered as part of the configuration management control.

If the software or firmware is embedded in the monitoring or measuring device, and not readily removable, then the device itself should be placed under configuration management control. (Refer to ISO 10007:1995.)

1) Has the organization determined the monitoring and measurement to be undertaken and the monitoring and the measuring devices needed to provide evidence of conformity of product to determined requirements (see Clause 7.2.1)?

2) Has the organization established processes to ensure that monitoring and measurement can be carried out?

3) Are these processes carried out in a manner that is consistent with the monitoring and measurement requirements?

4) Where necessary to ensure valid results, are the monitoring and measuring devices

   a) Calibrated or verified at specified intervals?
   b) Has the calibration been made against measurement standards traceable to international or national measurement standards?
   c) Where no such standards exist, has the basis used for calibration or verification been recorded?

5) Where necessary to ensure valid results, are the monitoring and measuring devices

   a) adjusted or re-adjusted as necessary?
   b) identified to enable the calibration status to be determined?
   c) safeguarded from adjustments that would invalidate the measurement result?
   d) protected from damage and deterioration during handling, maintenance, and storage?

6) Does the organization assess and record the validity of the previous measuring results when the monitoring and measuring devices are found not to conform to requirements?

7) Does the organization take appropriate action on the monitoring and measuring devices and any product affected?

8) Are records of the results of calibration and verification maintained?

9) When used in the monitoring and measurement of specified requirements, has the ability of computer software to satisfy the intended application been confirmed?

10) Has this confirmation been undertaken prior to initial use, and reconfirmed as necessary?

8. Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed
a) to demonstrate conformity of the product,
b) to ensure conformity of the quality management system, and
c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

This clause is the third aspect of planning required by ISO 9001:2000. Planning the monitoring and measurement of product and processes is normally carried out while planning the realization processes (see Clause 7.1). This clause also requires the planning of other activities, such as the QMS continual improvement processes, the internal audits, and the analysis of data.

Statistical techniques should be used, where feasible and cost-effective, in the monitoring and measurement of product and processes, as well as in the analysis of data.

1) Has the organization planned and implemented the monitoring, measurement, analysis, and improvement processes needed to

a) demonstrate conformity of the product?
b) ensure conformity of the QMS?

continual improvement: recurring activity to increase the ability to fulfill **requirements** (3.1.2)
NOTE The **process** (3.4.1) of establishing objectives and finding opportunities for improvement is a continual process through the use of **audit findings** (3.9.5) and **audit conclusions** (3.9.6) or other means and generally leads to **corrective (3.6.5)** or **preventive action** (3.6.4).

c) continually improve the effectiveness of the QMS?

2) Does this include determination of applicable methods, including statistical techniques, and the extent of their use?

☐ Who is responsible for the planning of the monitoring and measurement activities for
- determining conformity of the product?
- determining conformity of the QMS?
- continually improving the effectiveness of the QMS?

☐ Who determines the applicable methods of statistical techniques and where they apply?

☐ What forms are used and what is maintained in the organization's records?

☐ What training is provided in statistical techniques?

8.2 Monitoring and measuring

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

This clause requires an organization to close an important loop in the QMS, as required by Clause 1.1 b): "enhance customer satisfaction through the effective application of the system". Appropriate data must be obtained and used methodically, not just on an ad hoc basis. In order to be used as a measurement of the QMS performance, customer satisfaction data is usually analyzed (see Clause 8.4) to produce significant information for top

customer satisfaction: customer's perception of the degree to which the customer's **requirements** (3.1.2) have been fulfilled
NOTE 1 Customer complaints are a common indicator of

management to consider during management reviews (see Clause 5.6).

It is essential to understand that "customer satisfaction" as discussed in ISO 9001:2000, differs from "customer happiness". Clause 3.1.4 of ISO 9000:2000 defines customer satisfaction in terms of several key concepts: customers' perception, degree, and fulfilling customers' requirements (see the definition in the right-hand column). In determining whether a customer has been satisfied, an organization must measure the degree to which the customer's requirements have been fulfilled. An organization, when making this determination, need only target the needs or expectations that were "stated, generally implied or obligatory". Also key in determining whether customer satisfaction has been achieved is ensuring that the "customer's perception" is taken into account.

low customer satisfaction but their absence does not necessarily imply high customer satisfaction. NOTE 2 Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction. [ISO 9000, 3.1.4]

☐ Have customer satisfaction surveys or equivalents been implemented and monitored?

☐ Who is responsible for conducting such customer satisfaction surveys or equivalents?

☐ What happens to the results of the surveys?

There are many ways to monitor customer satisfaction. Massive mailings of customer surveys can be useful to organizations with a very large customer base. However, a good survey is expensive to develop and administer and, since the response rate is usually very low, it has to be sent to hundreds, if not thousands, of customers.

Small and medium-size organizations should explore other avenues.

An organization that has field service personnel can incorporate the collection of customer satisfaction data into regular field service activities. This approach is particularly effective in obtaining information about a product that has been in use for some time. An organization that has only a few customers can call each and every one to obtain his or her perceptions as to whether requirements have been met. A retail store can use cashiers to systematically obtain information on small and specific aspects of customer satisfaction, changing the aspect on a rotation basis at appropriate time intervals. Whatever method is used, it should be applied systematically.

1) Does the organization monitor information relating to customer perception as to whether the organization has met customer requirements?

2) Have the methods for obtaining and using this information been determined?

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system
a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

Internal audits should be planned and scheduled to encompass at least the elements of the QMS that are covered by the ISO 9001:2000 standard. They could also cover the other elements of the QMS, if this approach adds

audit:
systematic, independent and documented

value to the organization. Planning and scheduling can be as simple as performing a complete audit at prescribed intervals, or it can be elaborated and made more effective by carrying out audits of parts of the system, each audit having its interval and timing determined by the status and importance of the processes and areas.
In addition to the scheduled internal audits, an internal audit may be triggered for the following reasons:

- significant changes have been made, either in the organization or in the processes;
- an analysis of nonconformities and customer complaints points to a potential problem area in the organization;
- high employee turnover in a department;
- safety, performance, and dependability of products may be jeopardized due to nonconformities; and
- verification that an important corrective or preventive action has been taken and is effective.

The results of the internal audits should be documented (see Clause 4.2.4) and include, at least, a judgment on whether the QMS and its processes

- conform to the requirements, ie, QMS requirements, planned arrangements for product realization, requirements of ISO 9001, customer and legal requirements; and
- are effective in delivering the expected results.

The internal audit processes could also be defined and implemented with the broader objective of providing management with opportunities to improve the QMS (see Clause 8.5.1).

QMS procedures and work instructions will not always be available as audit criteria, especially in smaller organizations. It will be part of the audit preparation to identify, obtain, and become acquainted with the criteria necessary to arrive at valid audit conclusions. In some cases, an audit criterion could be an agreed-upon method or process that is not documented.

Some organizations will want to implement internal audit processes that cover other aspects of their management system, eg, the EMS or the H&SS, either in parallel or

process (3.4.1) for obtaining **audit evidence** (3.9.4) and evaluating it objectively to determine the extent to which **audit criteria** (3.9.3) are fulfilled [ISO 9000, 3.9.1]

audit evidence: records (3.7.6), statements of fact or other **information** (3.7.1) which are relevant to the **audit criteria** (3.9.3) and verifiable
NOTE Audit evidence can be qualitative or quantitative.
[ISO 9000, 3.9.4]

audit findings: results of the evaluation of the collected **audit evidence** (3.9.4) against **audit criteria** (3.9.3) [ISO 9000, 3.9.6]

auditor: person with the **competence** (3.9.12) to conduct an **audit** (3.9.1) [ISO 9000, 3.9.9]

nonconformity: non-fulfillment of a **requirement** (3.1.2) [ISO 9000, 3.6.2]

☐ Who is responsible for conducting and reporting audit results?

☐ How are auditors selected to ensure objectivity and impartiality of the audit?

simultaneously with the internal QMS audits. The ISO standard does not impose or prohibit any kind of approach. Making such joint internal audits — that is, having a single audit team carry out an internal audit covering both the EMS and the QMS requirements — will probably require a little more effort, but would certainly help harmonize the various aspects of the organization's management system.

1) Has the organization conducted internal audits at planned intervals to determine whether the QMS

a) conforms to the planned arrangements (see Clause 7.1)?
b) conforms to the requirements of ISO 9001:2000?
c) conforms to the QMS requirements established by the organization?
d) is effectively implemented and maintained?

2) Has an audit program been planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?

3) Have the audit criteria, scope, frequency, and methods been defined?

4) Does the selection of auditors and conduct of audits ensure the objectivity and impartiality of the audit process?

5) Is it verified that auditors do not audit their own work?

6) Have the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, been defined in a documented procedure?

7) Has the management responsible for the area being audited ensured that actions are taken without undue delay to eliminate detected nonconformities and their causes?

☐ Are the audits scheduled and conducted in accordance with documented procedures, using a written checklist or equivalent?

☐ Do the audit records show the deficiencies found and the

corrective actions required?

☐ Who is responsible for training personnel to audit the QMS?

☐ Are authorizations made for follow-up audits when required?

☐ Have internal quality audit staff been trained in auditing techniques?

☐ Are internal auditors competent to perform internal audits?

8) Do follow-up activities include the verification of the actions taken and the reporting of verification results (see Clause 8.5.2)?

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

Where appropriate, statistical control techniques should be used to identify adverse trends for both process and product before nonconformities actually occur.

Early identification of nonconformities, before the final stage of production or service delivery, increases the efficiency of the entire operation by eliminating further processing of nonconforming items.

1) Has the organization applied suitable methods for monitoring and, where applicable, measurement of the QMS processes?

2) Do these methods demonstrate the ability of the processes to achieve planned results?

3) When planned results are not achieved, has correction and corrective action been taken, as appropriate, to ensure conformity of the product?

corrective action:
action to eliminate the cause of a detected **nonconformity** (3.6.2) or other undesirable situation
NOTE 1 There can be more than one cause for a nonconformity.
NOTE 2 Corrective action is taken to prevent recurrence whereas **preventive action** (3.6.4) is taken to prevent occurrence.
NOTE 3 There is a distinction between **correction** (3.6.6) and corrective action.
[ISO 9000, 3.6.5]

correction:
action to eliminate a detected **nonconformity** (3.6.2)
NOTE 1 A correction can be made in conjunction with a **corrective action** (3.6.5).
NOTE 2 A correction can be, for example, **rework** (3.6.7) or

regrade (3.6.8).
[ISO 9000, 3.6.6]

☐ Who is responsible for
- determining which of the QMS processes need to be measured, and how they will be measured?

- monitoring the QMS processes?

☐ Do the results show that the processes achieve the planned results?

☐ What are the methods of handling corrective actions when the planned results are not achieved?

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The organization's procedures or quality plan (see Clause 7.1) should directly identify the final monitoring and measurement activities upon which the final release of product is based.

When offering the product for customer acceptance, the organization should validate the characteristics of the product in accordance with specified requirements, under conditions similar to those in the application (target) environment, as stated in the contract. Any differences between the validation environment and the actual application environment, and the risks associated with such differences, should be identified and justified as early in the life cycle as possible, and recorded.

Monitoring and measurement may be required at several levels, from the individual software item (unit tests), through integration and system and acceptance tests on the complete software product. At each level, the organization should consider, as appropriate

- monitoring and measurement objectives;
- type and sequence of monitoring and measurement to be performed;
- the degree of independence of the personnel developing the software from the personnel monitoring and measuring the product characteristics;
- the methods for controlling the environment, including tools, monitoring and measurement software, and input data used in monitoring or measuring product characteristics;
- expected results and pass/fail criteria;
- the method of recording, analyzing, and approving the monitoring and measurement results; and
- the methods for handling problems found during the monitoring and measurement activities.

The techniques described under Clauses 7.3.4–7.3.6 may also be relevant to monitoring and measurement activities.

☐ Who is responsible for determining what characteristics of the product are to be monitored and measured?

☐ Who performs the work and authorizes the release of the product?

☐ How is product held until inspection or testing is complete?

☐ How is non-conforming product identified?

☐ Who is responsible for determining the positive recall process?

☐ Who is responsible for releasing items subject to positive recall?

1) Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met?

2) Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see Clause 7.1)?

3) Is evidence of conformity with the acceptance criteria maintained?

4) Do the records indicate the person(s) authorizing release of product?

5) Is it ensured that product release and service delivery do not proceed until all the planned arrangements (see Clause 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer?

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:
a) by taking action to eliminate the detected nonconformity;
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to reverification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

When any product is found (eg, by monitoring and measurement) not to conform to the specified requirements, inadvertent use should be prevented.

nonconformity: non-fulfillment of a **requirement** (3.1.2) [ISO 9000, 3.6.2]

The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

☐ Who is responsible
- for identifying and holding nonconforming product?

- for reviewing and authorizing the disposition of nonconforming product?

An important element in addressing nonconformities is to give all appropriate personnel the freedom to identify nonconforming items, activities, and processes and encourage them to suggest improvements.

Information concerning nonconforming items should be provided to all appropriate personnel, so that action is taken, if necessary, to identify and correct the cause of the nonconformity, and prevent its recurrence (see

Clause 8.5.3). These records (see Clause 4.2.4) and their analysis contribute to the measurement of the effectiveness of the QMS.

Requests by the organization for concessions or changes in specification should be processed in accordance with documented procedures. The organization should ensure that such requests are clear and accurate. Any additional information, comment, or recommendation that might help the customer to arrive at a decision should be given. The customer's agreement to these concessions may form part of the contract with the organization.

Consideration should be given to the need for an investigation into the cause of the nonconformance. Records should be retained of

- any investigation into the cause of the nonconformance;
- corrective action taken; and
- disposition.

Rework (Reprocessing)

The control of rework (reprocessing) is an important feature of the disposition of nonconforming product.

Reworking of products should comply with an authorized and documented process that describes work instructions, equipment, and the method of inspection and tests to be used; results of rework should be recorded (see Clause 4.2.4).

The reworked products should meet the original or the formally revised specification. Any previous inspection and test that could have been invalidated by the reworking should be repeated, or else the results from the original inspection and test should be confirmed as still being applicable.

Changes to approved reworking procedures should be subject to formal approval.

Returned Products

Any product returned to the organization should be

☐ How are other functions in the organization that may be affected by a nonconformity notified?

☐ What are the applicable disposition categories?

☐ What information is provided to the relevant authority or, where applicable, the customer?

☐ What records are maintained, and where?

☐ Is corrected non-conforming product subject to re-verification?

☐ What is our process covering the actions to be taken when nonconforming product is detected after delivery or use has started?

treated as nonconforming product until it has satisfied a documented acceptance procedure. When applicable, consideration should be given to the handling of contaminated product.

Disposal of Nonconforming Product

Control should be established over the disposal of nonconforming product designated as scrap to ensure that

- its status is clearly identified (see Clause 7.5.3);
- it cannot be confused with conforming product;
- it cannot re-enter the production system; and
- it is disposed of safely.

SERVICE

When a service is delivered in the presence of the customer, a nonconformity is an important problem. The organization cannot take "action to eliminate the detected nonconformity", nor can it take "action to preclude its original intended use or application". The nonconforming service can only be accepted "under concession ... by the customer", which very often has a financial impact, and may mean losing a customer.

When nonconformities occur during service delivery, the organization's employee may not have the time to convene a review board that would decide on a proper disposition, and on the actions "appropriate to the effects, or potential effects, of the nonconformity". Organizations should therefore have predetermined action plans for all likely service nonconformities, and a knowledge of these action plans should be part of the competence requirements covered in Clause 6.2.2.

In software development, a configuration management process may be applied to implement a part or the whole of Clause 8.3. The organization should identify at what point, in the product life cycle, control and recording of nonconforming product is required.

Segregation of nonconforming items may be accomplished by transferring the item out of a

production or a testing (monitoring or measurement) environment and into a separate environment. For software items, these separate "environments" may simply be distinct libraries or directories, with different access capabilities, resident in a single computer system. In the case of embedded software, it may be necessary to separate the nonconforming item (hardware) that contains the nonconforming software.

In the disposition of software nonconformities, attention should be paid to the following aspects:

- any discovered problems and their possible impacts on any other parts of the product (hardware or software) should be noted and those responsible notified, so that the problems can be investigated and resolved;
- evaluation of the severity of a nonconformity and the consequences of its continued existence; and
- areas affected by any modifications to resolve a nonconformity should be identified and retested. The method for determining the scope of retesting should include evaluation of the need for "regression" tests to verify that no new nonconformities have been introduced.

With software, repair or rework to resolve a nonconformity results in a new version of the product.

Note that, in many instances, software product is delivered in a series of planned (phased) releases, with only the final delivery meeting the full set of customer requirements. As such, interim releases might be considered as nonconforming product, relative to the overall requirements. In these circumstances, the organization should ensure, prior to delivery, that the customer is aware of, and in agreement with, such planned releases.

1) Has the organization ensured that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery?

2) Have the controls and related responsibilities and authorities for dealing with nonconforming product been defined in a documented procedure?

3) Does the organization deal with nonconforming product by one or more of the following ways:

   a) taking action to eliminate the detected nonconformity?
   b) authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer?
   c) taking action to preclude its original intended use or application.

4) Have records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, been maintained?

5) When nonconforming product is corrected, is it subjected to reverification to demonstrate conformity to the requirements?

6) When nonconforming product is detected after delivery or use has started, does the organization take action appropriate to the effects, or potential effects, of the nonconformity?

8.4 Analysis of data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to
a) customer satisfaction (see 8.2.1),
b) conformity to product requirements (see 7.2.1),
c) characteristics and trends of processes and products including opportunities for preventive action, and
d) suppliers.

An organization usually generates a lot of data, which may be recorded. This data will relate to many aspects, such as finances, occupational safety and health, environment, legal affairs, and product information. The QMS will focus on product-related data, which may cover such topics as

- customer feedback;
- market share and competing products data;
- product performance on the market;
- trends in the market;
- trends from process control activities;
- trends from the measurement and monitoring of product characteristics;
- suppliers performance;
- human resources data such as turnover, employee suggestions, impact of recognitions, etc; and
- results in improvements efforts.

This data is normally too voluminous and too detailed to be useful during management reviews (see Clause 5.6). It is necessary to analyze the data and transform it into meaningful information, using techniques such as performance indicators, Pareto diagrams, and other statistical techniques. Although items a)–d) of Clause 8.4 require data for analysis from a minimum of four areas, it does not prescribe the use of any particular

☐ Has the organization determined who is responsible for data analysis?

☐ What actions are taken with the results of the analysis?

☐ Are the results of the analysis compared with previous results to evaluate if there have been improvements to the QMS?

☐ Are the results from the analysis of data one of the inputs into the management review process (see Clause 5.6)?

tool for analyzing it. Clause 8.4 is closely related Clause 8.5.1, on continual improvement.

1) Has the organization determined, collected, and analyzed appropriate data to demonstrate the suitability and effectiveness of the QMS?

2) Has the organization determined, collected, and analyzed appropriate data to evaluate where continual improvement of the QMS can be made?

3) Does this include data generated as a result of monitoring and measurement and from other relevant sources ?

4) Does the analysis of data provide information relating to

   a) customer satisfaction (see Clause 8.2.1)?
   b) conformance to product requirements (see Clause 7.2.1)?
   c) characteristics and trends of processes and products including opportunities for preventive action?
   d) suppliers?

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

In Clause 8.5.1, seven requirements of ISO 9001:2000 culminate in the requirement for continual improvement of the effectiveness of the QMS, with reference to: quality policy, quality objectives, audit results, analysis of data, corrective actions, preventive actions, and management review. References to improvement are also found in

continual improvement: recurring activity to increase the ability to fulfill **requirements** (3.1.2)

Clauses 1, 4.1, 5.1, 5.5.2, 6.1, and 8.1. Obviously, the concept of continual improvement is an integral part of ISO 9001:2000.

Clause 8.5.1 does not specifically require continual improvement of the technical processes (eg, continually reducing process variation) or of the products (eg, continually improving their value to customers), but the improvement of the effectiveness of the QMS. Given the definition of effectiveness in ISO 9000:2000 (see the definition in the right-hand column), Clause 8.5.1 requires that an organization improve its capacity to deliver products that meet all requirements, as defined in Clause 7.2.1.

The improvement of processes and products may occur as a consequence of the proper operation of the QMS, and particularly as a consequence of management review outputs (see Clause 5.6.3).

NOTE The **process** (3.4.1) of establishing objectives and finding opportunities for improvement is a continual process through the use of **audit findings** (3.9.5) and **audit conclusions** (3.9.6), analysis of data, management **reviews** (3.8.7) or other means and generally leads to **corrective action** (3.6.5) or **preventive action** (3.6.4).
[ISO 9000, 3.2.13]

effectiveness:
extent to which planned activities are realized and planned results achieved
[ISO 9000, 3.2.14]

1) Has the organization continually improved the effectiveness of the QMS through the use of

a) the quality policy?
b) quality objectives?
c) audit results?
d) analysis of data?
e) corrective and preventive actions?
f) management review?

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for
a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) records of the results of action taken (see 4.2.4), and
f) reviewing corrective action taken.

Information on corrective and preventive actions is required as an integral part of the management review process (see Clause 5.6), to maintain and improve the effectiveness of the QMS.

The relation between corrective and preventive action is illustrated in Figure 15. Both actions are initiated and carried out to a degree appropriate to the magnitude of the problem, and to the risk(s) encountered.

The organization should have documented procedures for identifying and eliminating the causes of actual or potential nonconformities in products, processes, or the QMS.

Causes of detected nonconformities should promptly be identified so that corrective action may be taken and recurrence prevented. These causes may include the following:

- failures, malfunctions, or nonconformities in incoming materials, processes, tools, equipment, or facilities in which products are processed, stored, or handled, including the equipment and systems therein;
- inadequate or non-existent procedures and documentation;
- noncompliance with procedures;

corrective action: action to eliminate the cause of a detected **nonconformity** (3.6.2) or other undesirable situation
NOTE 1 There can be more than one cause for a nonconformity.
NOTE 2 Corrective action is taken to prevent recurrence whereas **preventive action** (3.6.4) is taken to prevent occurrence.
NOTE 3 There is a distinction between **correction** (3.6.6) and corrective action.
[ISO 9000, 3.6.5]

☐ Does the procedure cover the reviewing of nonconformances and determining their cause?

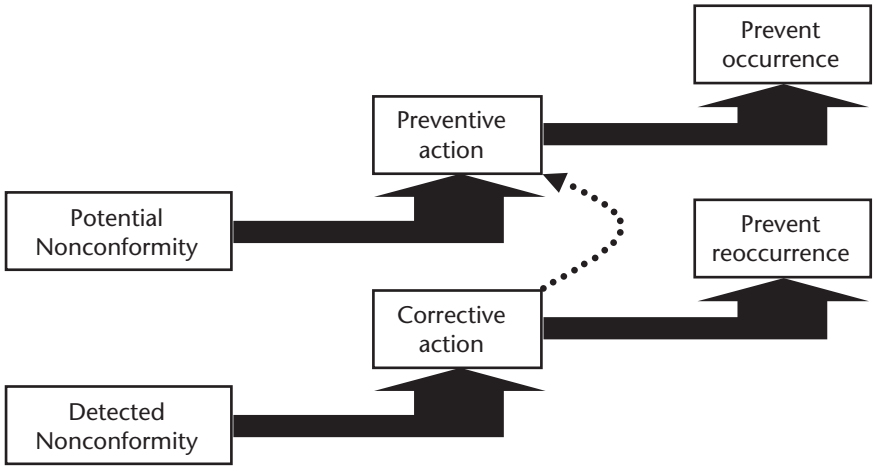


Figure 15
Corrective and Preventive Action

- inadequate process control;
- lack of training;
- inadequate working conditions;
- inadequate resources (human or material); and
- inherent process variability.

The conditions resulting from these causes may be revealed by analysis of the following:

- inspection and test records;
- nonconformity records;
- observations during process monitoring;
- audit observations;
- service or customer complaints;
- regulatory authority or customer observations;
- observations and reports by personnel;
- subcontract problems; and
- management review results.

The same causes and conditions may be involved in preventive action, where patterns or trends that may indicate the potential for occurrence of nonconformities should be investigated (see Clause 8.5.3). The degree of corrective or preventive action taken should be dependent upon and directly related to the risk, size, and

☐ Who is responsible for determining and implementing the actions needed to ensure that the nonconformity does not recur?

☐ Who is responsible for reviewing the results of the corrective actions taken and verifying that they are effective?

☐ What records are to be maintained? Where are they stored?

nature of the problems and their direct effects on product quality.

Corrective actions may include

- withholding products available for sale;
- withdrawing products from circulation;
- giving advice to customers (for example, checks to be carried out before use, additional guidance on the use of the product, or instructions on the replacement of certain products); and
- in extreme cases, recall of the product.

Key features of the documented procedure(s) necessary to effectively implement corrective action include

- clear and accurate identification of the product lot(s) concerned (which requires, in turn, comprehensive lot history documentation; see Clause 7.5.3);
- ability to identify problems in a timely manner and take appropriate action concerning related products/components;
- ability to identify in a timely manner the initial recipient(s) of defective product;
- a summary of activities, findings, and recommendations associated with the corrective action, prepared by a designated person who is able to assess the efficiency of any recall;
- an adequate and effective system for controlling corrective action, reviewed and challenged at defined intervals; and
- clear descriptions of the course(s) of action, with designated responsible persons identified.

An investigation record would typically include

- the name of the product;
- the date the complaint was received;
- any control number used;
- the name and address of the complainant;
- the nature of the complaint; and
- the results of the investigation, including
  - the corrective action taken;
  - the justification, if no action is taken;
  - the dates of the investigation;

– the name of the investigator; and
– the reply (if any) to the complainant.

1) Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence?

2) Are corrective actions appropriate to the effects of the nonconformities encountered?

3) Has a documented procedure been established to define requirements for

   a) reviewing nonconformities (including customer complaints)?
   b) determining the causes of nonconformities?
   c) evaluating the need for action to ensure that nonconformities do not recur?
   d) determining and implementing the action needed?
   e) recording the results of action taken?
   f) reviewing corrective action taken?

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for
a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken (see 4.2.4), and
e) reviewing preventive action taken.

Corrective action is taken after nonconformities are identified. Preventive action is taken when a potential nonconformity is identified as a result of the analysis of

preventive action: action to eliminate the

records and other relevant sources of information, such as the following:

- statistical process control documents;
- complaints from customer or other sources;
- purchased items, rejected on receipt, that need rework; and
- internal and supplier products, processes, and QMS information.

Records relating to the performance of the product should be analyzed regularly to detect any trends and to identify areas of risk that may lead to potential nonconformities. The analyses should also determine the actions necessary to prevent any identified potential problems. See too Clause 8.5.2.

Information on corrective and preventive actions taken is required as an integral part of the management review process (see Clause 5.6) to maintain and improve the effectiveness of the QMS.

1) Has the organization determined the actions to eliminate the causes of potential nonconformities in order to prevent their occurrence?

2) Are preventive actions appropriate to the effects of the potential problems?

3) Has a documented procedure been established to define requirements for

   a) determining potential nonconformities and their causes?
   b) evaluating the need for action to prevent occurrence of nonconformities?
   c) determining and implementing action needed?
   d) recording the results of action taken (see Clause 4.2.4)?
   e) reviewing preventive action taken?

cause of a potential **nonconformity** (3.6.2) or other potentially undesirable situation
NOTE 1 There can be more than one cause for a potential nonconformity.
NOTE 2 Preventive action is taken to prevent occurrence whereas **corrective action** (3.6.5) is taken to prevent recurrence.
[ISO 9000, 3.6.4]

☐ Does the procedure cover the need for determining where preventive actions should be taken and the actions to be taken to prevent occurrence of nonconformities?

☐ Who is responsible for implementing the necessary actions to prevent occurrence of nonconformities?

☐ Who is responsible for determining the effectiveness of the procedure?

☐ What records are to be maintained? Where are they stored?

Appendix A
ISO 9000:2000 family of Standards

ISO 9000:2000	Quality management systems — Fundamentals and vocabulary
ISO 9000-2:97	Quality management and quality assurance standards — Part 2: Generic guidelines for the application of ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994
ISO 9000-3:97	Quality management and quality assurance — Guidelines for the application of ISO 9001:94 to the design, development, supply, installation and maintenance of computer software
ISO 9000-4:93	Quality management and quality assurance standards — Guide to dependability programme management
ISO 9001:2000	Quality management systems — Requirements
ISO 9004:2000	Quality management systems — Guidelines for performance improvements
ISO 9004-2:91	Quality management and quality system elements — Part 2: Guidelines for services
ISO 9004-3:93	Quality management and quality system elements — Part 3: Guidelines for processed materials
ISO 9004-4:93	Quality management and quality system elements — Part 4: Guidelines for quality improvement
ISO 10005:95	Quality management — Guidelines for quality plans
ISO 10006:97	Quality management — Guidelines to quality in project management
ISO 10007:95	Quality management — Guidelines for configuration management
ISO 10011-1:90	Guidelines for auditing quality systems — Part 1: Auditing
ISO 10011-2:91	Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors
ISO 10011-3:91	Guidelines for auditing quality systems — Part 3: Management of audit programs
ISO 10012-1:92	Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment

ISO/FDIS 10012-2:96	Quality assurance for measuring equipment — Part 2: Controls of measurement processes
ISO 10013:95	Guidelines for developing quality manuals
ISO 10014:99	Guideline for managing the economics of quality
ISO/CD2 19011:2001	Guidelines on quality and environmental management systems auditing

Appendix B
ISO 9000:2000 — Vocabulary Clause
Alphabetical Order

ISO/TC 176 prepared a set of guidelines, the *Product Introduction Package,* which contains numerous modules. This Appendix reprints the definitions of vocabulary from ISO 9000:2000, together with excerpts from the module called "Guidance on the Terminology used in ISO 9001:2000 and ISO 9004:2000".

In preparing the ISO 9000:2000 family of Standards, and to assist in their readability and translatability, great care has been taken to use the correct English words and terms to describe the concepts and requirements. The objective is to use simple, technically accurate terms and, to the greatest extent possible, rely on common dictionary definitions. As with most technical subjects, some terms have very specific meanings that differ from their more common dictionary definition. In all other cases common dictionary definitions are used. Definitions of terms in ISO 9000:2000 have normative status and take precedence over common dictionary definitions. These normative definitions are included in the table below.

Audit # 3.9.1	systematic, independent and documented **process** (3.4.1) for obtaining **audit evidence** (3.9.4) and evaluating it objectively to determine the extent to which **audit criteria** (3.9.3) are fulfilled
Audit client # 3.9.7	**organization** (3.3.1) or person requesting an **audit** (3.9.1)
Audit conclusion # 3.9.6	outcome of an **audit** (3.9.1) provided by the **audit team** (3.9.10) after consideration of all the audit objections and all audit findings (3.9.5)
Audit criteria # 3.9.3	set of policies, **procedures** (3.4.5) or **requirements** (3.1.2) used as a reference
Audit evidence # 3.9.4	**records** (3.7.6), statements of fact or other **information** (3.7.1) which are relevant to the **audit criteria** (3.9.3) and verifiable NOTE Audit evidence can be qualitative or quantitative.
Audit findings # 3.9.5	results of the evaluation of the collected **audit evidence** (3.9.4) against **audit criteria** (3.9.3)

Audit programme # 3.9.2	set of one or more **audits** (3.9.1) planned for a specific time frame and directed towards a specific purpose
Audit team # 3.9.10	one or more **auditors** conducting an **audit** (3.9.1) NOTE 1 One auditor in the audit team is generally appointed as audit team leader. NOTE 2 The audit team can include auditors-in-training and, where required, **technical experts** (3.9.11). NOTE 3 Observers can accompany the audit team but do not act as part of it.
Auditee # 3.9.8	**organization** (3.3.1) being audited
Auditor # 3.9.9	person with the competence to conduct an **audit** (3.9.1)
Capability # 3.1.5	ability of an **organization** (3.3.1), **system** (3.2.1) or **process** (3.4.1) to realize a **product** (3.4.2) that will fulfill the **requirements** (3.1.2) for that product NOTE Process capability terms in the field of statistics are defined in ISO 3534-2.
Characteristic # 3.5.1	distinguishing feature NOTE 1 A characteristic can be inherent or assigned. NOTE 2 A characteristic can be qualitative or quantitative. NOTE 3 There are various classes of characteristic, such as the following: — physical (eg, mechanical, electrical, chemical or biological characteristics); — sensory (eg, related to smell, touch, taste, sight, hearing); — behavioral (eg, courtesy, honesty, veracity); — temporal (eg, punctuality, reliability, availability); — ergonomic (eg, physiological characteristic, or related to human safety); — functional (eg, maximum speed of an aircraft).
Competence 3.14 ISO/CD3 19011	*demonstrated capability to apply knowledge and skills*
Concession # 3.6.11	permission to use or release a **product** (3.4.2) that does not conform to specified requirements (3.1.2) NOTE A concession is generally limited to the delivery of a product that has nonconforming **characteristics** (3.5.1) within specified limits for an agreed time or quantity of that product.

Conformity # 3.6.1	fulfillment of a **requirement** (3.1.2) NOTE This definition is consistent with ISO/IEC Guide 2 but differs from it in phrasing to fit into the ISO 9000 concepts. NOTE 2 The term "conformance" is synonymous but deprecated.
Continual Improvement # 3.2.13	recurring activity to increase the ability to fulfill requirements (3.1.2) NOTE The **process** (3.4.1) of establishing objectives and finding opportunities for improvement is a continual process through the use of **audit findings** (3.9.5) and **audit conclusions** (3.9.6), analysis of data, management **reviews** (3.8.7) or other means and generally leads to **corrective** (3.6.5) or **preventive action** (3.6.4).
Correction # 3.6.6	action to eliminate a detected **nonconformity** (3.6.2) NOTE 1 A correction can be made in conjunction with a **corrective action** (3.6.5). NOTE 2 A correction can be, for example, **rework** (3.6.7) or **regrade** (3.6.8).
Corrective action # 3.6.5	action to eliminate the cause of a detected **nonconformity** (3.6.2) or other undesirable situation NOTE 1 There can be more than one cause for a nonconformity. NOTE 2 Corrective action is taken to prevent recurrence whereas **preventive action** (3.6.4) is taken to prevent occurrence. NOTE 3 There is a distinction between **correction** (3.6.6) and corrective action.
Criteria, audit # 3.9.3	set of policies, **procedures** (3.4.5) or **requirements** (3.1.2) used as a reference
Customer # 3.3.5	**organization** (3.3.1) or person that receives a **product** (3.4.2) EXAMPLE Consumer, client, end-user, retailer, beneficiary and purchaser. NOTE A customer can be internal or external to the organization.
Customer satisfaction # 3.1.4	customer's perception of the degree to which the customer's **requirements** (3.1.2) have been fulfilled NOTE 1 Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction. NOTE 2 Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

Defect # 3.6.3	non-fulfillment of a **requirement** (3.1.2) related to an intended or specified use NOTE 1 The distinction between the concepts defect and **nonconformity** (3.6.2) is important as it has legal connotations, particularly those associated with product liability issues. Consequently the term "defect" should be used with extreme caution. NOTE 2 The intended use as intended by the **customer** (3.3.5) can be affected by the nature of the information, such as operating or maintenance instructions, provided by the **supplier** (3.3.6).
Dependability # 3.5.3	collective term used to describe the availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance NOTE Dependability is used only for general descriptions in non-quantitative terms.
Design and development # 3.4.4	set of **processes** (3.4.1) that transforms **requirements** (3.1.2) into specified **characteristics** (3.5.1) or into the **specification** (3.7.3) of a **product** (3.4.2), **process** (3.4.1) or **system** (3.2.1). NOTE 1 The terms "design" and "development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development process. NOTE 2 A qualifier can be applied to indicate the nature of what is being designed and developed (eg, product design and development or process design and development).
Deviation permit # 3.6.12	permission to depart from the originally specified **requirements** (3.1.2) of a **product** (3.4.2) prior to realization NOTE A deviation permit is generally given for a limited quantity of product or period of time, and for a specific use.
Document # 3.7.2	**information** (3.7.1) and its supporting medium EXAMPLES **Record** (3.7.6), **specification** (3.7.3), procedure document, drawing, report, standard. NOTE 1 The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or a combination thereof. NOTE 2 A set of documents, for example specifications and records, is frequently called "documentation". NOTE 3 Some **requirements** (3.1.2) (eg, the requirement to be readable) relate to all types of documents, however there can be different requirements for specifications (eg, the requirement to be revision controlled) and records (eg, the requirement to be retrievable).

Effectiveness # 3.2.14	extent to which planned activities are realized and planned results achieved
Efficiency # 3.2.15	relationship between the result achieved and the resources used
Grade # 3.1.3	category or rank given to different quality **requirements** (3.1.2) for **products** (3.4.2), **processes** (3.4.1) or **systems** (3.2.1) having the same functional use EXAMPLE Class of airline ticket and category of hotel in a hotel guide. NOTE When establishing a quality requirement, the grade is generally specified.
Information # 3.7.1	meaningful data
Infrastructure # 3.3.3	<organization> system set of facilities, equipment and services needed for the operation of an **organization** (3.3.1)
Inspection # 3.8.2	conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging [ISO/IEC Guide 2]
Interested party # 3.3.7	person or group having an interest in the performance or success of an **organization** (3.3.1) EXAMPLE **Customers** (3.3.5), owners, people in an organization, **suppliers** (3.3.6), bankers, unions, partners or society. NOTE A group can comprise an organization, a part thereof, or more than one organization.
Management # 3.2.6	coordinated activities to direct and control an **organization** (3.3.1) NOTE In English, the term "management" sometimes refers to people, i.e. a person or group of people with authority and responsibility for the conduct and control of an organization. When "management" is used in this sense it should always be used with some form of qualifier to avoid confusion with the concept "management" defined above. For example, "management shall..." is deprecated whereas "**top management** (3.2.7) shall..." is acceptable.
Management system # 3.2.2	**system** (3.2.1) to establish policy and objectives and to achieve those objectives NOTE A management system of an **organization** (3.3.1) can include different management systems, such as a **quality management system** (3.2.3), a financial management system or an environmental management system.

Measurement control system # 3.10.1	set of interrelated or interacting elements necessary to achieve **metrological confirmation** (3.10.3) and continual control of **measurement processes** (3.10.2)
Measurement process # 3.10.2	set of operations to determine the value of a quantity
Measuring equipment # 3.10.4	measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a **measurement process** (3.10.2)
Metrological characteristic # 3.10.5	distinguishing feature which can influence the results of measurement NOTE 1 **Measuring equipment** (3.10.4) usually has several metrological characteristics. NOTE 2 Metrological characteristics can be the subject of calibration.
Metrological confirmation # 3.10.3	set of operations required to ensure that **measuring equipment** (3.10.4) conforms to the **requirements** (3.1.2) for its intended use NOTE 1 Metrological confirmation generally includes calibration or **verification** (3.8.4), any necessary adjustment or **repair** (3.6.9), and subsequent recalibration, comparison with the metrological requirements for the intended use of the equipment, as well as any required sealing and labelling. NOTE 2 Metrological confirmation is not achieved until and unless the fitness of the measuring equipment for the intended use has been demonstrated and documented. NOTE 3 The requirements for intended use include such considerations as range, resolution, maximum permissible errors, etc. NOTE 4 Metrological confirmation requirements are usually distinct from and are not specified in product requirements.
Metrological function # 3.10.6	functions with organizational responsibility for defining and implementing the **measurement control system** (3.10.1)
Nonconformity # 3.6.2	non-fulfillment of a **requirement** (3.1.2)
Objective evidence # 3.8.1	data supporting the existence or verity of something NOTE Objective evidence may be obtained through observation, measurement, **test** (3.8.3), or other means.

Organization # 3.3.1	group of people and facilities with an arrangement of responsibilities, authorities and relationships EXAMPLE Company, corporation, firm, enterprise, institution, charity, sole trader, association, or parts or combination thereof. NOTE 1 The arrangement is generally orderly. NOTE 2 An organization can be public or private. NOTE 3 This definition is valid for the purposes of **quality management system** (3.2.3) standards. The term "organization" is defined differently in ISO/IEC Guide 2.
Organizational structure # 3.3.2	arrangement of responsibilities, authorities and relationships between people NOTE 1 The arrangement is generally orderly. NOTE 2 A formal expression of the organizational structure is often provided in a **quality manual** (3.7.4) or a **quality plan** (3.7.5) for a **project** (3.4.3). NOTE 3 The scope of an organizational structure can include relevant interfaces to external **organizations** (3.3.1).
Preventive action # 3.6.4	action to eliminate the cause of a potential **nonconformity** (3.6.2) or other potentially undesirable situation NOTE 1 There can be more than one cause for a potential nonconformity NOTE 2 Preventive action is taken to prevent occurrence whereas **corrective action** (3.6.5) is taken to prevent recurrence.
Procedure # 3.4.5	specified way to carry out an activity or a **process** (3.4.1) NOTE 1 Procedures can be documented or not. NOTE 2 When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used. The **document** (3.7.2) that contains a procedure can be called a "procedure document".
Process # 3.4.1	set of interrelated or interacting activities which transforms inputs into outputs NOTE 1 Inputs to a process are generally outputs of other processes. NOTE 2 Processes in an **organization** (3.3.1) are generally planned and carried out under controlled conditions to add value. NOTE 3 A process where the **conformity** (3.6.1) of the resulting **product** (3.4.2) cannot be readily or economically verified is frequently referred to as a "special process".

Product # 3.4.2	result of a **process** (3.4.1) NOTE 1 There are four generic product categories as follows: — services (eg, transport); — software (eg, computer program, dictionary); — hardware (eg, engine mechanical part); — processed materials (eg, lubricant). Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example the offered product "automobile" consists of hardware (eg, tyres), processed materials (eg, fuel, cooling liquid), software (eg, engine control software, driver's manual), and service (eg, operating explanations given by the salesman). NOTE 2 Service is the result of at least one activity necessarily performed at the interface between the **supplier** (3.3.6) and **customer** (3.3.5) and is generally intangible. Provision of a service can involve, for example, the following: — an activity performed on a customer-supplied tangible product (eg, automobile to be repaired); — an activity performed on a customer-supplied intangible product (eg, the income statement needed to prepare a tax return); — the delivery of an intangible product (eg, the delivery of information in the context of knowledge transmission); — the creation of ambience for the customer (eg, in hotels and restaurants). Software consists of information and is generally intangible and can be in the form of approaches, transactions or **procedures** (3.4.5). Hardware is generally tangible and its amount is a countable **characteristic** (3.5.1). Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods. NOTE 3 **Quality assurance** (3.2.11) is mainly focused on intended **product.**

Project # 3.4.3	unique **process** (3.4.1), consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific **requirements** (3.1.2), including the constraints of time, cost and resources NOTE 1 An individual project can form part of a larger project structure. NOTE 2 In some projects the objectives are refined and the product **characteristics** (3.5.1) defined progressively as the project proceeds. NOTE 3 The outcome of a project may be one or several units of **product** (3.4.2). NOTE 4 Adapted from ISO 10006:1997.
Qualification process # 3.8.6	**process** (3.4.1) to demonstrate the ability to fulfill specified **requirements** (3.1.2) NOTE 1 The term "qualified" is used to designate the corresponding status. NOTE 2 Qualification can concern persons, **products** (3.4.2), processes or **systems** (3.2.1). EXAMPLE Auditor qualification process (3.9.13), material qualification process.
Quality # 3.1.1	degree to which a set of inherent **characteristics** (3.5.1) fulfills **requirements** (3.1.2) NOTE 1 The term "quality" can be used with adjectives such as poor, good or excellent. NOTE 2 "Inherent", as opposed to "assigned", means existing in something, especially as a permanent characteristic.
Quality assurance # 3.2.11	part of **quality management** (3.2.8) focused on providing confidence that quality **requirements** (3.1.2) will be fulfilled
Quality characteristic # 3.5.2	inherent **characteristic** (3.5.1) of a **product** (3.4.2), **process** (3.4.1) or **system** (3.2.1) related to a **requirement** (3.1.2) NOTE 1 Inherent means existing in something, especially as a permanent characteristic. NOTE 2 A characteristic assigned to a product, process or system (eg, the price of a product, the owner of a product) is not a quality characteristic of that product, process or system.
Quality control # 3.2.10	part of **quality management** (3.2.8) focused on fulfilling quality **requirements** (3.1.2)
Quality improvement # 3.2.12	part of **quality management** (3.2.8) focused on increasing the ability to fulfill quality **requirements** (3.1.2) NOTE The requirements can be related to any aspect such as **effectiveness** (3.2.14), **efficiency** (3.2.15) or **traceability** (3.5.4).

Quality management # 3.2.8	coordinated activities to direct and control an **organization** (3.3.1) with regard to **quality** (3.1.1) NOTE Direction and control with regard to quality generally includes establishment of the **quality policy** (3.2.4) and **quality objectives** (3.2.5), **quality planning** (3.2.9), **quality control** (3.2.10), **quality assurance** (3.2.11) and **quality improvement** (3.2.12).
Quality management system # 3.2.3	**management system** (3.2.2) to direct and control an **organization** (3.3.1) with regard to **quality** (3.1.1)
Quality manual # 3.7.4	**document** (3.7.2) specifying the **quality management system** (3.2.3) of an **organization** (3.3.1) NOTE Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.
Quality objective # 3.2.5	something sought, or aimed for, related to **quality** (3.1.1) NOTE 1 Quality objectives are generally based on the organization's **quality policy** (3.2.4). NOTE 2 Quality objectives are generally specified for relevant functions and levels in the **organization** (3.3.1).
Quality plan # 3.7.5	**document** (3.7.2) specifying which **procedures** (3.4.5) and associated resources shall be applied by whom and when to a specific **project** (3.4.3), **product** (3.4.2), **process** (3.4.1) or contract NOTE 1 These procedures generally include those referring to quality management processes and to product realization processes. NOTE 2 A quality plan often makes reference to parts of the **quality manual** (3.7.4) or to procedure documents. NOTE 3 A quality plan is generally one of the results of **quality planning** (3.2.9).
Quality planning #3.2.9	part of **quality management** (3.2.8) focused on setting **quality objectives** (3.2.5) and specifying necessary operational **processes** (3.4.1) and related resources to fulfill the quality objectives NOTE Establishing **quality plans** (3.7.5) can be part of quality planning.

Quality policy # 3.2.4	overall intentions and direction of an **organization** (3.3.1) related to **quality** (3.1.1) as formally expressed by **top management** (3.2.7) NOTE 1 Generally the quality policy is consistent with the overall policy of the organization and provides a framework for the setting of **quality objectives** (3.2.5). NOTE 2 Quality management principles presented in this International Standard can form a basis for the establishment of a quality policy (See 0.2).
Record # 3.7.6	**document** (3.7.2) stating results achieved or providing evidence of activities performed NOTE 1 Records can be used to document **traceability** (3.5.4) and to provide evidence of **verification** (3.8.4), **preventive action** (3.6.4) and **corrective action** (3.6.5). NOTE 2 Generally records need not be under revision control.
Regrade # 3.6.8	alteration of the **grade** (3.1.3) of a nonconforming **product** (3.4.2) in order to make it conform to **requirements** (3.1.2) differing from the initial ones
Release # 3.6.13	permission to proceed to the next stage of a **process** (3.4.1) NOTE In English, in the context of computer software, the term release is frequently used to refer to a version of the software itself.
Repair # 3.6.9	action taken on a nonconforming product (3.4.2) to make it acceptable for the intended use NOTE 1 Repair includes remedial action taken on a previously conforming product to restore it for use, for example as part of maintenance. NOTE 2 Unlike **rework** (3.6.7), repair can affect or change parts of the nonconforming product.
Requirement # 3.1.2	need or expectation that is stated, generally implied or obligatory NOTE 1 "Generally implied" means that it is custom or common practice for the **organization** (3.3.1), its **customers** (3.3.5) and other **interested parties** (3.3.7), that the expectation under consideration is implied. NOTE 2 A qualifier can be used to denote a specific type of requirement, eg, product requirement, quality management requirement, customer requirement. NOTE 3 A specified requirement is one which is stated, for example, in a **document** (3.7.2). NOTE 4 Requirements can be generated by different interested parties.

Review # 3.8.7	activity undertaken to determine the suitability, adequacy and **effectiveness** (3.2.14) of the subject matter to achieve established objectives NOTE Review can also include the determination of **efficiency** (3.2.15). EXAMPLE Management review, design and development review, review of customer requirements and nonconformity review.
Rework # 3.6.7	action on a nonconforming **product** (3.4.2) to make it conform to the **requirements** (3.1.2) NOTE Unlike rework, **repair** (3.6.9) can affect or change parts of the nonconforming product.
Scrap # 3.6.10	action on a nonconforming **product** (3.4.2) to preclude its originally intended use EXAMPLE Recycling, destruction. NOTE In a nonconforming service situation, use is precluded by discontinuing the service.
Specification # 3.7.3	**document** (3.7.2) stating **requirements** (3.1.2) NOTE A specification can be related to activities (e.g. procedure document, process specification and test specification), or **products** (3.4.2) (eg, product specification, performance specification and drawing).
Supplier # 3.3.6	**organization** (3.3.1) or person that provides a **product** (3.4.2) EXAMPLE Producer, distributor, retailer or vendor of a product, or provider of a service or information. NOTE 1 A supplier can be internal or external to the organization. NOTE 2 In a contractual situation a supplier is sometimes called “contractor”.
System # 3.2.1	set of interrelated or interacting elements
Technical expert # 3.9.11	<audit> person who provides specific knowledge of, or expertise on, the subject to be audited
Test #3.8.3	determination of one or more **characteristics** (3.5.1) according to a **procedure** (3.4.5)
Top management # 3.2.7	person or group of people who directs and controls an **organization** (3.3.1) at the highest level

Traceability # 3.5.4	ability to trace the history, application or location of that which is under consideration NOTE 1 When considering **product** (3.4.2), traceability can relate to: — the origin of materials and parts; — the processing history; — the distribution and location of the product after delivery. NOTE 2 In the field of metrology the definition of VIM:1993, 6.10, is the accepted definition.
Validation # 3.8.5	confirmation, through the provision of **objective evidence** (3.8.1), that the **requirements** (3.1.2) for a specific intended use or application have been fulfilled. NOTE 1 The term "validated" is used to designate the corresponding status. NOTE 2 The use conditions for validation can be real or simulated.
Verification # 3.8.4	confirmation, through the provision of **objective evidence** (3.8.1), that specified **requirements** (3.1.2) have been fulfilled NOTE 1 The term "verified" is used to designate the corresponding status. NOTE 2 Confirmation can comprise activities such as — performing alternative calculations, — comparing a new design **specification** (3.7.3) with a similar proven design specification, — undertaking **tests** (3.8.3) and demonstrations, and — reviewing documents prior to issue.
Work environment # 3.3.4	set of conditions under which work is performed NOTE Conditions include physical, social, psychological and environmental factors (such as temperature, recognition schemes, ergonomics and atmospheric composition).

Appendix C
Correspondence between ISO 9001:1994 and ISO 9001:2000

Table 1
Correspondence between ISO 9001:1994 and ISO 9001:2000

ISO 9001:1994	ISO 9001:2000
4.1 Management responsibility [title only]	
4.1.1 Quality policy	5.1 + 5.3 + 5.4.1
4.1.2 Organization [title only]	
4.1.2.1 Responsibility and authority	5.5.1
4.1.2.2 Resources	6.1 + 6.2.1
4.1.2.3 Management representative	5.5.2
4.1.3 Management review	5.6.1 + 8.5.1
4.2 Quality system [title only]	
4.2.1 General	4.1 + 4.2.2
4.2.2 Quality system procedures	4.2.1
4.2.3 Quality planning	5.4.2 + 6.2.1 + 7.1
4.3 Contract review [title only]	
4.3.1 General	
4.3.2 Review	5.2 + 7.2.1 + 7.2.2 + 7.2.3
4.3.3 Amendment to a contract	7.2.2
4.3.4 Records	7.2.2
4.4 Design control [title only]	
4.4.1 General	
4.4.2 Design and development planning	7.3.1
4.4.3 Organizational and technical interfaces	7.3.1
4.4.4 Design input	7.2.1 + 7.3.2
4.4.5 Design output	7.3.3
4.4.6 Design review	7.3.4
4.4.7 Design verification	7.3.5
4.4.8 Design validation	7.3.6
4.4.9 Design changes	7.3.7
4.5 Document and data control [title only]	

ISO 9001:1994	ISO 9001:2000
4.5.1 General	4.2.3
4.5.2 Document and data approval and issue	4.2.3
4.5.3 Document and data changes	4.2.3
4.6 Purchasing [title only]	
4.6.1 General	
4.6.2 Evaluation of subcontractors	7.4.1
4.6.3 Purchasing data	7.4.2
4.6.4 Verification of purchased product	7.4.3
4.7 Control of customer-supplied product	7.5.4
4.8 Product identification and traceability	7.5.3
4.9 Process control	6.3 + 6.4 + 7.5.1 + 7.5.2
4.10 Inspection and testing [title only]	
4.10.1 General	7.1 + 8.1
4.10.2 Receiving inspection and testing	7.4.3 + 8.2.4
4.10.3 In-process inspection and testing	8.2.4
4.10.4 Final inspection and testing	8.2.4
4.10.5 Inspection and test records	7.5.3 + 8.2.4
4.11 Control of inspection, measuring and test equipment [title only]	
4.11.1 General	7.6
4.11.2 Control procedure	7.6
4.12 Inspection and test status	7.5.3
4.13 Control of nonconforming product[title only]	
4.13.1 General	8.3
4.13.2 Review and disposition of nonconforming product	8.3
4.14 Corrective and preventive action [title only]	
4.14.1 General	8.5.2 + 8.5.3
4.14.2 Corrective action	8.5.2
4.14.3 Preventive action	8.5.3

ISO 9001:1994	ISO 9001:2000
4.15 Handling, storage, packaging, preservation & delivery [title only]	
4.15.1 General	
4.15.2 Handling	7.5.5
4.15.3 Storage	7.5.5
4.15.4 Packaging	7.5.5
4.15.5 Preservation	7.5.5
4.15.6 Delivery	7.5.1
4.16 Control of quality records	4.2.4
4.17 Internal quality audits	8.2.2 + 8.2.3
4.18 Training	6.2.2
4.19 Servicing	7.5.1
4.20 Statistical techniques [title only]	
4.20.1 Identification of need	8.1 + 8.2.3 + 8.2.4 + 8.4
4.20.2 Procedures	8.1 + 8.2.3 + 8.2.4 + 8.4

Appendix D
Correspondence between ISO 9001:2000 and ISO 9001:1994

ISO 9001:2000	ISO 9001:1994
4 Quality management system [title only]	
4.1 General requirements	4.2.1
4.2 Documentation requirements [title only]	
4.2.1 General	4.2.2
4.2.2 Quality manual	4.2.1
4.2.3 Control of documents	4.5.1 + 4.5.2 + 4.5.3
4.2.4 Control of quality records	4.16
5 Management responsibility [title only]	
5.1 Management commitment	4.1.1
5.2 Customer focus	4.3.2
5.3 Quality policy	4.1.1
5.4 Planning [title only]	
5.4.1 Quality objectives	4.1.1
5.4.2 Quality management system planning	4.2.3
5.5 Responsibility, authority and communication [title only]	
5.5.1 Responsibility and authority	4.1.2.1
5.5.2 Management representative	4.1.2.3
5.5.3 Internal communication	
5.6 Management review [title only]	
5.6.1 General	4.1.3
5.6.2 Review input	
5.6.3 Review output	
6 Resource management [title only]	
6.1 Provision of resources	4.1.2.2
6.2 Human resources [title only]	
6.2.1 General	4.1.2.2
6.2.2 Competence, awareness and training	4.18
6.3 Infrastructure	4.9
6.4 Work environment	4.9

ISO 9001:2000	ISO 9001:1994
7 Product realization [title only]	
7.1 Planning of product realization	4.2.3 + 4.10.1
7.2 Customer-related processes [title only]	
7.2.1 Determination of requirements related to the product	4.3.2 + 4.4.4
7.2.2 Review of requirements related to the product	4.3.2 + 4.3.3 + 4.3.4
7.2.3 Customer communication	4.3.2
7.3 Design and development [title only]	
7.3.1 Design and development planning	4.4.2 + 4.4.3
7.3.2 Design and development inputs	4.4.4
7.3.3 Design and development outputs	4.4.5
7.3.4 Design and development review	4.4.6
7.3.5 Design and development verification	4.4.7
7.3.6 Design and development validation	4.4.8
7.3.7 Control of design and development changes	4.4.9
7.4 Purchasing [title only]	
7.4.1 Purchasing process	4.6.2
7.4.2 Purchasing information	4.6.3
7.4.3 Verification of purchased product	4.6.4 + 4.10.2
7.5 Production and service provision [title only]	
7.5.1 Control of production and service provision	4.9 + 4.15.6 + 4.19
7.5.2 Validation of processes for production and service provision	4.9
7.5.3 Identification and traceability	4.8 + 4.10.5 + 4.12
7.5.4 Customer property	4.7
7.5.5 Preservation of product	4.15.2 + 4.15.3 + 4.15.4 + 4.15.5
7.6 Control of monitoring and measuring devices	4.11.1 + 4.11.2
8 Measurement, analysis and improvement [title only]	

ISO 9001:2000	ISO 9001:1994
8.1 General	4.10.1 + 4.20.1 + 4.20.2
8.2 Monitoring and measurement [title only]	
8.2.1 Customer satisfaction	
8.2.2 Internal audit	4.17
8.2.3 Monitoring and measurement of processes	4.17 + 4.20.1 + 4.20.2
8.2.4 Monitoring and measurement of product	4.10.2 + 4.10.3 + 4.10.4 + 4.10.5 + 4.20.1 + 4.20.2
8.3 Control of nonconforming product	4.13.1 + 4.13.2
8.4 Analysis of data	4.20.1 + 4.20.2
8.5 Improvement [title only]	
8.5.1 Continual improvement	4.1.3
8.5.2 Corrective action	4.14.1 + 4.14.2
8.5.3 Preventive action	4.14.1 + 4.14.3

Appendix E
Correspondence between ISO 9001:2000 ISO 14001:1996

Table E.1 — Correspondence between ISO 9001:2000 and ISO 14001:1996

ISO 9001:2000		ISO 14001:1996	
Introduction			**Introduction**
General	0.1		
Process approach	0.2		
Relationship with ISO 9004	0.3		
Compatibility with other management systems	0.4		
Scope	**1**	**1**	**Scope**
General	1.1		
Application	1.2		
Normative reference	**2**	**2**	**Normative references**
Terms and definitions	**3**	**3**	**Definitions**
Quality management system	**4**	**4**	**Environmental management system requirements**
General requirements	4.1	4.1	General requirements
Documentation requirements	4.2		
General	4.2.1	4.4.4	Environmental management system documentation
Quality manual	4.2.2	4.4.4	Environmental management system documentation
Control of documents	4.2.3	4.4.5	Document control
Control of records	4.2.4	4.5.3	Records
Management responsibility	**5**	4.4.1	Structure and responsibility
Management commitment	5.1	4.2	Environmental policy
		4.4.1	Structure and responsibility
Customer focus	5.2	4.3.1	Environmental aspects
		4.3.2	Legal and other requirements
Quality policy	5.3	4.2	Environmental policy
Planning	5.4	4.3	Planning
Quality objectives	5.4.1	4.3.3	Objectives and targets
Quality management system planning	5.4.2	4.3.4	Environmental management programme(s)

(Continued)

Table E.1 (Continued)

ISO 9001:2000		ISO 14001:1996	
Responsibility, authority and communication	5.5	4.1	General requirements
Responsibility and authority Management representative	5.5.1 5.5.2	4.4.1	Structure and responsibility
Internal communication	5.5.3	4.4.3	Communication
Management review General Review input Review output	5.6 5.6.1 5.6.2 5.6.3	4.6	Management review
Resource management	**6**	4.4.1	Structure and responsibility
Provision of resources Human resources General	6.1 6.2 6.2.1		
Competence, awareness and training	6.2.2	4.4.2	Training, awareness and competence
Infrastructure Work environment	6.3 6.4	4.4.1	Structure and responsibility
Product realization	**7**	4.4 4.4.6	Implementation and operation Operational control
Planning of product realization Customer-related processes	7.1 7.2	4.4.6	Operational control
Determination of requirements related to the product	7.2.1	4.3.1 4.3.2 4.4.6	Environmental aspects Legal and other requirements Operational control
Review of requirements related to the product	7.2.2	4.4.6 4.3.1	Operational control Environmental aspects
Customer communication	7.2.3	4.4.3	Communications
Design and development Design and development planning Design and development inputs Design and development outputs Design and development review Design and development verification Design and development validation	7.3 7.3.1 7.3.2 7.3.3 7.3.4 7.3.5 7.3.6	4.4.6	Operational control

(Continued)

Table E.1 (Concluded)

ISO 9001:2000		ISO 14001:1996	
Control of design and development changes	7.3.7		
Purchasing	7.4	4.4.6	Operational control
Purchasing process	7.4.1		
Purchasing information	7.4.2		
Verification of purchased product	7.4.3		
Production and service provision	7.5	4.4.6	Operational control
Control of production and service provision	7.5.1		
Validation of processes for production and service provision	7.5.2		
Identification and traceability	7.5.3		
Customer property	7.5.4		
Preservation of product	7.5.5		
Control of monitoring and measuring devices	7.6	4.5.1	Monitoring and measurement
Measurement, analysis and improvement	**8**	4.5	Checking and corrective action
General	8.1	4.5.1	Monitoring and measurement
Monitoring and measurement	8.2		
Customer satisfaction	8.2.1		
Internal audit	8.2.2	4.5.4	Environmental management system audit
Monitoring and measurement of processes	8.2.3	4.5.1	Monitoring and measurement
Monitoring and measurement of product	8.2.4		
Control of nonconforming product	8.3	4.5.2	Nonconformance and corrective and preventive action
		4.4.7	Emergency preparedness and response
Analysis of data	8.4	4.5.1	Monitoring and measurement
Improvement	8.5	4.2	Environmental policy
Continual improvement	8.5.1	4.3.4	Environmental management programme(s)
Corrective action	8.5.2	4.5.2	Nonconformance and corrective and preventive action
Preventive action	8.5.3		

Table E.2 — Correspondence between ISO 14001:1996 and ISO 9001:2000

ISO 14001:1996		ISO 9001:2000	
Introduction	—	**0**	**Introduction**
		0.1	General
		0.2	Process approach
		0.3	Relationship with ISO 9004
		0.4	Compatibility with other management systems
Scope	**1**	**1**	**Scope**
		1.1	General
		1.2	Application
Normative references	**2**	**2**	**Normative reference**
Definitions	**3**	**3**	**Terms and definitions**
Environmental management system requirements	**4**	**4**	**Quality management system**
General requirements	4.1	4.1	General requirements
		5.5	Responsibility, authority and communication
		5.5.1	Responsibility and authority
Environmental policy	4.2	5.1	Management commitment
		5.3	Quality policy
		8.5	Improvement
Planning	4.3	5.4	Planning
Environmental aspects	4.3.1	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
Legal and other requirements	4.3.2	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
Objectives and targets	4.3.3	5.4.1	Quality objectives
Environmental management programme(s)	4.3.4	5.4.2	Quality management system planning
		8.5.1	Continual improvement
Implementation and operation	4.4	**7**	**Product realization**
		7.1	Planning of product realization

(Continued)

Table E.2 (Continued)

ISO 14001:1996		ISO 9001:2000	
Structure and responsibility	4.4.1	**5**	**Management responsibility**
		5.1	Management commitment
		5.5.1	Responsibility and authority
		5.5.2	Management representative
		6	**Resource management**
		6.1	Provision of resources
		6.2	Human resources
		6.2.1	General
		6.3	Infrastructure
		6.4	Work environment
Training, awareness and competence	4.4.2	6.2.2	Competence, awareness and training
Communication	4.4.3	5.5.3	Internal communication
		7.2.3	Customer communication
Environmental management system documentation	4.4.4	4.2	Documentation requirements
		4.2.1	General
		4.2.2	Quality manual
Document control	4.4.5	4.2.3	Control of documents
Operational control	4.4.6	**7**	**Product realization**
		7.1	Planning of product realization
		7.2	Customer-related processes
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
		7.3	Design and development
		7.3.1	Design and development planning
		7.3.2	Design and development inputs
		7.3.3	Design and development outputs
		7.3.4	Design and development review
		7.3.5	Design and development verification
		7.3.6	Design and development validation
		7.3.7	Control of design and development changes
		7.4	Purchasing
		7.4.1	Purchasing process

(Continued)

Table E.2 (Concluded)

ISO 14001:1996		ISO 9001:2000	
		7.4.2	Purchasing information
		7.4.3	Verification of purchased product
		7.5	Production and service provision
		7.5.1	Control of production and service provision
		7.5.2	Validation of processes for production and service provision
		7.5.3	Identification and traceability
		7.5.4	Customer property
		7.5.5	Preservation of product
		7.5.2	Validation of processes for production and service provision
Emergency preparedness and response	4.4.7	8.3	Control of nonconforming product
Checking and corrective action	4.5	**8**	**Measurement, analysis and improvement**
Monitoring and measurement	4.5.1	7.6	Control of monitoring and measuring devices
		8.1	General
		8.2	Monitoring and measurement
		8.2.1	Customer satisfaction
		8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
		8.4	Analysis of data
Nonconformance and corrective and preventive action	4.5.2	8.3	Control of nonconforming product
		8.5.2	Corrective action
		8.5.3	Preventive action
Records	4.5.3	4.2.4	Control of records
Environmental management system audit	4.5.4	8.2.2	Internal audit
Management review	4.6	5.6	Management review
		5.6.1	General
		5.6.2	Review input
		5.6.3	Review output

Appendix F
Bibliography, Internet Resources, and Contact Information

F1. Standards and Related Documents

F1.1 CSA Publications

CAN/CSA-ISO 9000-00,
Quality management systems — Fundamentals and vocabulary;

CAN/CSA-ISO 9000-4-96,
Quality management and quality assurance standards — Part 4: Guide to dependability programme management;

CAN/CSA-ISO 9001-00,
Quality management systems — Requirements;

CAN/CSA-ISO 9004-00,
Quality management systems — Guidelines for performance improvements;

CAN/CSA-ISO 10005-96,
Quality management — Guidelines for quality plans;

CAN/CSA-ISO 10006-98,
Quality management — Guidelines to quality in project management;

CAN/CSA-ISO 10007-95,
Quality management — Guidelines for configuration management;

CAN/CSA-ISO 10011-1-94,
Guidelines for auditing quality systems — Part 1: Auditing (to be revised as ISO 19011, *Guidelines for auditing management systems*);

CAN/CSA-ISO 10011-2-94,
Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors (to be revised as ISO 19011, *Guidelines for auditing management systems*);

CAN/CSA-ISO 10011-3-97,
Guidelines for auditing quality systems — Part 3: Management of audit programmes (to be revised as ISO 19011, *Guidelines for auditing management systems*);

CAN/CSA-ISO 10012-1-97,
Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment (to be revised as ISO 10012, *Quality assurance requirements for measuring equipment*);

CAN/CSA-ISO 10012-2-98,
Quality assurance for measuring equipment — Part 2: Guidelines for control of measurement processes (to be revised as ISO 10012, *Quality assurance requirements for measuring equipment*);

CAN/CSA-ISO 10013-95,
Guidelines for developing quality manuals;

CAN/CSA-ISO TR 10014-99,
Guidelines for managing the economics of quality;

CAN/CSA-ISO 10015-00,
Quality management — Guidelines for training;

CAN/CSA-ISO TR 10017-00,
Guidance on statistical techniques for ISO 9001:1994;

CAN/CSA-ISO 14001-96,
Environmental management systems — Specification with guidance for use;

CAN/CSA-ISO 14004-6,
Environmental management systems — General guidelines on principles, systems and supporting techniques.

F1.2 ISO Publications

9000-3:1997,
Quality management and quality assurance standards — Part 3: Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software;

9004-2:1991,
Quality management and quality system elements — Part 2: Guidelines for services;

9004-3:1993,
Quality management and quality system elements — Part 3: Guidelines for processed materials;

9004-4:1993,
Quality management and quality system elements — Part 4: Guidelines for quality improvement;

TR 13425:1995,
Guide for the selection of statistical methods in standardization and specification;

14971:2000,
Medical devices — Application of risk management to medical devices;

19011 (forthcoming),
Guidelines on quality and/or environmental management systems auditing;

ISO/IEC 17025:1999,
General requirements for the competence of testing and calibration laboratories (formerly designated ISO/IEC Guide 25);

N56,
ISO/TC 176/PMG Interpretations;

N474,
Transition Planning Guidance;

ISO 9000: Small businesses — What to do — Advice from ISO/TC 176;

Product Introduction Package. 1. "Guidance on ISO 9001:2000, Clause 1.2, "Application" (ISO/TC 176/SC2/N524); 2. "Guidance on the Documentation Requirements of ISO 9001:2000" (ISO/TC 176/SC2/N525); 3. "Guidance on the Terminology used in ISO 9001:2000 and ISO 9004:2000" (ISO/TC 176/SC2/N526). 2000–.

Process Validation Guidance (available at no charge from the Medical Devices Global Harmonization Task Force Web site at <www.ghtf.org>);

Quality management principles and guidelines on their application (available at no charge from the ISO/TC 176/SC 2/N 376 Web site at
< http://www.bsi.org.uk/iso-tc176-sc2>);

Statistical methods for quality control. Vol.1: Terminology and symbols — Acceptance sampling. Vol.2: Measurement methods and results — Interpretation of statistical data — Process control. ISO Handbook, 4th edition, 1995.

F2. Internet Resources

<www.bsi.org.uk/iso-tc176-sc2>

- Detailed information from the British Standards Institute (BSI) about the ISO 9001/9004 revision program; updated on a regular basis.
- *Quality management principles and guidelines on their application*

<www.csa.ca>

- Database of "Official Interpretations" issued by ISO/TC 176 (CSA is the ISO/TC 176 Secretariat)

<www.ghtf.org>

- *Process Validation Guidance* (produced by the Medical Devices Global Harmonization Task Force)

<www.iaf.nu>

- International Accreditation Forum (IAF) Web site (see sections 1.2 and 3.1 of this handbook)

<www.iso.ch>

- General information regarding the ISO 9000:2000 family revision program
- ISO/IEC Directives, Parts 1, 2, and 3

<www.tc176.org>

- General information on the structure and work program of ISO/TC176
- *Product Introduction Package*. 1. "Guidance on ISO 9001:2000, Clause 1.2, "Application"; 2. "Guidance on the Documentation Requirements of ISO 9001:2000"; 3. "Guidance on the Terminology used in ISO 9001:2000 and ISO 9004:2000".
- Links to related password-protected and public Web sites

F3. Contact Information

ISO Technical Committee 176
Canadian Standards Association
178 Rexdale Boulevard
Toronto, ON M9W 1R3
Canada

Telephone: +1 416 747-4000
Telefax: +1 416 747-2473

Index

A

C

D

I

M

N

O

P

Q

R

S

T

V

W

ISBN 1-55324-451-6